

**PROSPECTUS SUPPLEMENT NO. 5**  
**(To Prospectus dated June 24, 2024)**



**Plus Therapeutics, Inc.**

This prospectus supplement updates and supplements the prospectus, dated June 24, 2024 (as supplemented to date, the “Prospectus”), which forms a part of our registration statement on Form S-1 ([No. 333-280061](#)). This prospectus supplement is being filed to update and supplement the information in the Prospectus with the information contained in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 14, 2024 (the “Form 10-Q”). Accordingly, we have attached the Form 10-Q to this prospectus supplement.

This prospectus supplement should be read in conjunction with the Prospectus, which is to be delivered with this prospectus supplement, and is qualified by reference thereto, except to the extent that the information in this prospectus supplement updates or supersedes the information contained in the Prospectus. Please keep this prospectus supplement with your Prospectus for future reference.

Our common stock, par value \$0.001 per share (“Common Stock”) is listed on The Nasdaq Capital Market LLC under the symbol “PSTV”. On November 13, 2024, the closing price of our Common Stock was \$1.31.

We are a “smaller reporting company” for purposes of federal securities laws and are subject to reduced public company reporting requirements. Accordingly, the information in the Prospectus and this prospectus supplement may not be comparable to information provided by companies that are not smaller reporting companies.

**Our business and investment in our Common Stock involve significant risks. These risks are described in the section titled “Risk Factors” beginning on page 13 of the Prospectus, and under similar headings in any amendments or supplements to the Prospectus.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of the Prospectus or this prospectus supplement. Any representation to the contrary is a criminal offense.**

**The date of this prospectus supplement is November 14, 2024.**

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2024

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-34375



**PLUS THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

DELAWARE  
(State or other jurisdiction  
of incorporation or organization)

4200 Marathon Blvd., Suite 200, Austin, TX  
(Address of principal executive offices)

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

78756  
(Zip Code)

(737) 255-7194

(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

As of November 7, 2024, there were 5,896,333 shares of the registrant's common stock outstanding.

**PLUS THERAPEUTICS, INC.**  
**Form 10-Q**

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## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

*This quarterly report on Form 10-Q 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. Statements other than statements of historical fact constitute “forward-looking statements.” These forward-looking statements do not constitute guarantees of future performance. These forward-looking statements may be identified by terms such as “intend,” “expect,” “project,” “believe,” “anticipate,” “initiate,” “will,” “should,” “would,” “could,” “may,” “designed,” “potential,” “evaluate,” “hypothesize,” “plan,” “progressing,” “proceeding,” “exploring,” “opportunity,” “hopes,” “suggest,” and similar expressions, or the negative of such expressions. Such statements are based upon certain assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate.*

*These statements include, without limitation, statements about our anticipated expenditures, including research and development, and general and administrative expenses; our strategic collaborations and license agreements, intellectual property, U.S. Food and Drug Administration and European Medicines Agency 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 quarterly report on Form 10-Q, including our potential need for additional financing and the availability thereof; our ability to integrate into our business and operations, develop, fully utilize and monetize acquired assets; 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 and medical device product manufacturing to a contract drug and medical device manufacturing organization; and the potential enhancement of our cash position through development, marketing, and licensing arrangements; and a material security breach or cybersecurity attack affecting our operations and property. The forward-looking statements included in this quarterly report on Form 10-Q 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, 2023, in other subsequent filings with the Securities and Exchange Commission, and under “Part II – Item 1A – Risk Factors” in this quarterly report on Form 10-Q. 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 to fund our operations in the near term and long term, on terms acceptable to us or at all; the outcome of our partnering/licensing efforts, risks associated with laws or regulatory requirements applicable to us, including the ability to come into compliance with The Nasdaq Capital Market listing requirements; market conditions, product performance, potential litigation, our ability to integrate into our business and operations, develop, fully utilize and monetize acquired assets, competition within the radiotherapeutics, and more generally, oncological medicine fields; and challenges associated with radiotherapeutic manufacturing, production and distribution capabilities necessary to support our clinical trials and any commercial level product demand, among others. The forward-looking statements included in this quarterly report on Form 10-Q 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, 2023, and under “Part II – Item 1A – Risk Factors” in this quarterly report on Form 10-Q. 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 “Part II – Item 1A – Risk Factors” in this quarterly report on Form 10-Q carefully. We caution you not to place undue reliance on the forward-looking statements contained in this quarterly report on Form 10-Q. These statements, like all statements in this quarterly report on Form 10-Q, speak only as of the date of this quarterly report on Form 10-Q (unless an earlier date is indicated) and the Company undertakes 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. Condensed Consolidated Financial Statements**

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

	<u>September 30, 2024</u>	<u>December 31, 2023</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 1,223	\$ 8,554
Investments	3,565	—
Other current assets	576	1,280
Total current assets	<u>5,364</u>	<u>9,834</u>
Property and equipment, net	591	906
Operating lease right-of-use assets	106	202
Goodwill	372	372
Intangible assets, net	513	42
Other assets	32	32
Total assets	<u>\$ 6,978</u>	<u>\$ 11,388</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 7,912	\$ 6,631
Operating lease liability	68	120
Deferred grant liability	840	—
Line of credit	3,292	—
Term loan obligation, current	—	3,976
Total current liabilities	<u>12,112</u>	<u>10,727</u>
Noncurrent operating lease liability	40	85
Deferred grant liability	—	1,924
Total liabilities	<u>12,152</u>	<u>12,736</u>
Commitments and contingencies (Note 10)		
Stockholders' deficit:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 1,952 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 6,154,758 and 5,896,333 issued and outstanding at September 30, 2024, and 4,522,656 issued and 4,444,097 outstanding as of December 31, 2023, respectively	6	5
Treasury stock (at cost, 258,425 and 78,559 shares as of September 30, 2024 and December 31, 2023, respectively)	(500)	(126)
Additional paid-in capital	484,896	479,274
Accumulated deficit	(489,576)	(480,501)
Total stockholders' deficit	<u>(5,174)</u>	<u>(1,348)</u>
Total liabilities and stockholders' deficit	<u>\$ 6,978</u>	<u>\$ 11,388</u>

See Accompanying Notes to these Condensed Consolidated Financial Statements

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Grant revenue	\$ 1,456	\$ 1,240	\$ 4,412	\$ 3,600
Operating expenses:				
Research and development	2,858	2,493	8,394	6,896
General and administrative	2,397	1,998	6,813	6,167
Total operating expenses	<u>5,255</u>	<u>4,491</u>	<u>15,207</u>	<u>13,063</u>
Loss from operations	(3,799)	(3,251)	(10,795)	(9,463)
Other income (expense):				
Financing expense	—	—	(3,545)	—
Change in fair value of warrants	960	—	5,654	—
Warrant issuance costs	(54)	—	(486)	—
Interest income	80	119	219	290
Interest expense	(61)	(87)	(122)	(333)
Total other income (expense)	<u>925</u>	<u>32</u>	<u>1,720</u>	<u>(43)</u>
Net loss	<u>\$ (2,874)</u>	<u>\$ (3,219)</u>	<u>\$ (9,075)</u>	<u>\$ (9,506)</u>
Per share information:				
Net loss per share of common stock - basic	\$ (0.37)	\$ (1.00)	\$ (1.46)	\$ (3.54)
Weighted average number of shares of common stock outstanding - basic	7,855,763	3,225,351	6,232,123	2,688,232
Net loss per share of common stock - diluted	\$ (0.37)	\$ (1.00)	\$ (1.67)	\$ (3.54)
Weighted average number of shares of common stock outstanding - diluted	7,855,763	3,225,351	8,452,338	2,688,232

See Accompanying Notes to these Condensed Consolidated Financial Statements

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

	Preferred stock		Convertible preferred stock		Common stock		Treasury Stock		Additional paid-in	Accumulated	Total stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	capital	deficit	(deficit)/equity
Balance at December 31, 2022	—	\$ —	1,952	\$ —	2,240,092	\$ 2	—	\$ —	\$ 473,628	\$ (467,185)	\$ 6,445
Stock-based compensation	—	—	—	—	—	—	—	—	140	—	140
Sale of common stock, net	—	—	—	—	168,164	—	—	—	895	—	895
Issuance of Series F preferred stock	1	—	—	—	—	—	—	—	1	—	1
Net loss	—	—	—	—	—	—	—	—	—	(4,805)	(4,805)
Balance at March 31, 2023	1	\$ —	1,952	\$ —	2,408,256	\$ 2	—	\$ —	\$ 474,664	\$ (471,990)	\$ 2,676
Redemption of Series F preferred stock	(1)	—	—	—	—	—	—	—	—	—	—
Fractional adjustment	—	—	—	—	(1,310)	—	—	—	—	—	—
Sale of common stock, net	—	—	—	—	472,674	1	—	—	1,327	—	1,328
Share-based compensation	—	—	—	—	—	—	—	—	140	—	140
Net loss	—	—	—	—	—	—	—	—	—	(1,482)	(1,482)
Balance at June 30, 2023	—	—	1,952	\$ —	2,879,620	\$ 3	—	\$ —	\$ 476,131	\$ (473,472)	\$ 2,662
Sale of common stock, net	—	—	—	—	1,589,655	2	—	—	2,954	—	2,956
Issuance of common stock for in process research and development	—	—	—	—	53,381	—	—	—	75	—	75
Stock-based compensation	—	—	—	—	—	—	—	—	148	—	148
Net loss	—	—	—	—	—	—	—	—	—	(3,219)	(3,219)
Balance at September 30, 2023	—	—	1,952	\$ —	4,522,656	\$ 6	—	\$ —	\$ 479,308	(476,691)	\$ 2,622
Balance at December 31, 2023	—	\$ —	1,952	\$ —	4,522,656	\$ 5	(78,559)	\$ (126)	\$ 479,274	\$ (480,501)	\$ (1,348)
Stock-based compensation	—	—	—	—	—	—	—	—	146	—	146
Purchase of treasury stock	—	—	—	—	—	—	(179,866)	(374)	—	—	(374)
Net loss	—	—	—	—	—	—	—	—	—	(3,261)	(3,261)
Balance at March 31, 2024	—	\$ —	1,952	\$ —	4,522,656	\$ 5	(258,425)	\$ (500)	\$ 479,420	\$ (483,762)	\$ (4,837)
Issuance of common stock	—	—	—	—	1,439,988	1	—	—	—	—	1
Stock-based compensation	—	—	—	—	—	—	—	—	151	—	151
Net loss	—	—	—	—	—	—	—	—	—	(2,940)	(2,940)
Balance at June 30, 2024	—	\$ —	1,952	\$ —	5,962,644	\$ 6	(258,425)	\$ (500)	\$ 479,571	\$ (486,702)	\$ (7,625)
Reclass of warrants to equity	—	—	—	—	—	—	—	—	5,200	—	5,200
Stock-based compensation	—	—	—	—	—	—	—	—	125	—	125
Exercise of pre-funded warrants	—	—	—	—	192,114	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	(2,874)	(2,874)
Balance at September 30, 2024	—	\$ —	1,952	\$ —	6,154,758	\$ 6	(258,425)	\$ (500)	\$ 484,896	\$ (489,576)	\$ (5,174)

See Accompanying Notes to these Condensed Consolidated Financial Statements

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

For the Nine Months Ended September 30,

	2024	2023
<b>Cash flows used in operating activities:</b>		
Net loss	\$ (9,075)	\$ (9,506)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	524	477
Amortization of deferred financing costs and debt discount	20	160
Share-based compensation expense	422	428
Accretion of discount on short-term investments	(70)	—
Non-cash financing expense	3,545	—
Change in fair value of warrants	(5,654)	—
Loss on disposal of property and equipment	—	2
Amortization of operating lease right-of-use assets	96	86
Stock issued for research and development	—	75
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Grant receivable	—	(91)
Other current assets	704	3,190
Accounts payable and accrued expenses	1,326	(4,061)
Change in operating lease liabilities	(97)	(87)
Deferred grant liability	(1,084)	(1,643)
Net cash used in operating activities	<u>(9,343)</u>	<u>(10,970)</u>
<b>Cash flows used in investing activities:</b>		
Purchases of property and equipment	(135)	(118)
Redemption of short-term investments	3,650	—
Purchase of short-term investments	(7,145)	—
Purchase of intangible assets	(545)	—
Net cash used in investing activities	<u>(4,175)</u>	<u>(118)</u>
<b>Cash flows provided by financing activities:</b>		
Principal payments of term loan obligation	(3,996)	(1,206)
Proceeds from credit facility	3,292	—
Purchase of treasury stock	(374)	—
Proceeds from sale of common stock, net of offering costs of \$0.2 million	—	5,180
Proceeds from sale of common stock, warrants and pre-funded warrants, net	7,265	—
Net cash provided by financing activities	<u>6,187</u>	<u>3,974</u>
Net decrease in cash and cash equivalents	<u>(7,331)</u>	<u>(7,114)</u>
Cash and cash equivalents at beginning of period	8,554	18,120
Cash and cash equivalents at end of period	<u>\$ 1,223</u>	<u>\$ 11,006</u>
<b>Supplemental disclosure of cash flows information:</b>		
Cash paid during period for:		
Interest	\$ 32	\$ 186
<b>Supplemental schedule of non-cash investing and financing activities:</b>		
Unpaid offering cost	\$ —	\$ 1
Right-of-use assets obtained in exchange for operating lease liability	\$ —	\$ 71
Common stock issued in payment for in process research and development	\$ —	\$ 75

See Accompanying Notes to these Condensed Consolidated Financial Statements

**PLUS THERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**September 30, 2024**  
**(UNAUDITED)**

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

The accompanying unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2024 and 2023 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, 2023 has been derived from the audited financial statements at December 31, 2023, 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.

On May 17, 2024, Plus Therapeutics, Inc. (the “Company”) established a wholly owned subsidiary, CNSide Diagnostics, LLC (“CNSide LLC”), a Delaware limited liability company. CNSide LLC was set up to operate the CNSide diagnostic portfolio, consisting of the intellectual property acquired by the Company from Biocept, Inc. (“Biocept”) in April 2024 (See Note 8, Biocept Asset Acquisitions, for further details).

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 the Company and its wholly owned subsidiary, CNSide LLC, have been included. Operating results for the three and nine months ended September 30, 2024 are not necessarily indicative of the results that may be expected for the remainder of the year ending December 31, 2024. These condensed consolidated 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, 2023, filed with the Securities and Exchange Commission on March 5, 2024.

**Grant Revenue Recognition**

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

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

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

**Warrants**

Warrants are accounted for as either derivative liabilities or as equity instruments depending on the specific terms of the agreement in accordance with applicable accounting guidance provided in ASC Topic 815 - *Derivatives and Hedging*. Equity-classified instruments are recorded in additional paid-in capital at issuance and are not subject to remeasurement. Liability-classified warrants are recorded at fair value at each reporting period with any change in fair value recognized as a component of change in fair value of warrants in the condensed consolidated statements of operations. The Company periodically evaluates changes in facts and circumstances that could impact the classification of warrants.

**Available-for-Sale Securities**

The Company’s available-for-sale securities consist of U.S. government and agency securities. Securities with maturities from the date of purchase of less than three months are included in cash equivalents. The Company classifies its marketable securities as available-for-sale and records such assets at estimated fair value in the condensed consolidated balance sheets, with unrealized gains and losses, if any, reported as a component of other comprehensive income (loss) within the condensed consolidated statements of operations and comprehensive income/loss and as a separate component of stockholders’ equity. Realized gains and losses are calculated on the specific identification method and recorded as interest income (loss). At each balance sheet date, the

Company assesses available-for-sale securities in an unrealized loss position to determine whether the decline in fair value below amortized cost is a result of credit losses or other factors, whether the Company expects to recover the amortized cost of the security, the Company's intent to sell and if it is more likely than not that the Company will be required to sell the securities before the recovery of amortized cost. The Company records changes in allowance for expected credit loss in other income (expense). There has been no allowance for expected credit losses recorded during any of the periods presented.

Any premium arising at purchase is amortized to the earliest call date and any discount arising at purchase is accreted to maturity. Accretion of discounts are recorded in interest income in the condensed consolidated statements of operations and comprehensive income/loss.

During the three and nine months ended September 30, 2024, the unrealized gain on the Company's available-for-sale securities was less than \$1,000, and not presented separately in the condensed consolidated statement of operations.

### **Recently Issued Accounting Pronouncements**

In December 2023, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update (ASU) No. 2023-09 Income Taxes (Topic 740): Improvements to Income Tax Disclosure. This ASU includes amendments that further enhance income tax disclosures, primarily through standardization and disaggregation of rate reconciliation categories and income taxes paid by jurisdiction. The ASU is effective for years beginning after December 15, 2024, but early adoption is permitted. This ASU should be applied on a prospective basis, although retrospective application is permitted. Management is currently evaluating the impact of the changes required by the new standard on the Company's consolidated financial statements and related disclosures.

In November 2023, the FASB issued Accounting Standard Update (ASU) No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. The new standard is intended to improve annual and interim reportable segment disclosure requirements regardless of number of reporting units, primarily through enhanced disclosures of significant expenses. The amendment requires public entities to disclose significant segment expenses that are regularly provided to the CODM and included within each reported measure of segment profit and loss. This update is effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years starting after December 15, 2024. This ASU must be applied retrospectively to all prior periods presented. Management is currently evaluating the impact of the changes required by the new standard on the Company's consolidated financial statements and related disclosures.

## **2. Use of Estimates**

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions affecting the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated 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 and warrant liability.

## **3. Liquidity and Going Concern**

The Company incurred a net loss of \$9.1 million for the nine months ended September 30, 2024. The Company had an accumulated deficit of \$489.6 million as of September 30, 2024. Additionally, the Company used net cash of \$9.3 million to fund its operating activities for the nine months ended September 30, 2024.

To date, the Company's operating losses have been funded primarily from outside sources of invested capital from issuance of its common and preferred stocks, proceeds from its term loan, line of credit facility and grant funding. However, the Company has had, and will continue to have, an ongoing need to raise additional cash from outside sources to fund its future clinical development programs and other operations. There can be no assurance that the Company will be able to continue to raise additional capital in the future. The Company's inability to raise additional cash would have a material and adverse impact on its operations and could cause the Company to default on its term loan. These factors raise substantial doubt about the Company's ability to continue as a going concern.

At the closing of the May 2024 Private Placement (as defined below), the Company received aggregate up-front gross proceeds of approximately \$7.3 million, before deducting fees and other expenses associated with the closing of the May 2024 Private Placement. None of the Series A and Series B Warrants issued in connection with May 2024 Private Placement were exercised as of September 30, 2024. See Note 12 to the unaudited condensed consolidated financial statements, Stockholders' Deficit - May 2024 Private Placement, for further details.

### *Nasdaq Listing Compliance*

On March 8, 2024, the Company received a written notice (the "Notice") from the Listing Qualifications staff of The Nasdaq Stock Market LLC ("Nasdaq"), notifying the Company that it no longer complied with the requirement under Nasdaq Listing

Rule 5550(b)(1) to maintain a minimum of \$2.5 million in stockholders' equity (the "Minimum Stockholders' Equity Requirement") for continued listing on The Nasdaq Capital Market or the alternative requirements of having a market value of listed securities of \$35 million or net income from continuing operations of \$500,000 in the most recently completed fiscal year or two of the last three most recently completed fiscal years.

On September 5, 2024, Nasdaq notified the Company that it had not regained compliance with Nasdaq Listing Rule 5550(b)(1) and that, as a result, unless the Company timely requests an appeal of this determination to a Nasdaq Hearings Panel (the "Panel"), Nasdaq would move to suspend trading of the Company's common stock and to have the Company's shares of common stock delisted from The Nasdaq Capital Market. The Company timely requested a hearing before the Panel, and the hearing was held on October 22, 2024.

On October 30, 2024, the Company received a decision from the Panel, notifying the Company that it had until March 4, 2025, to demonstrate compliance with the Minimum Stockholders' Equity Requirement. The Panel also required that the Company file a public disclosure on or before March 4, 2025 and describe the transactions undertaken by the Company to achieve compliance and demonstrate long-term compliance with the Minimum Stockholders' Equity Requirement. The Panel also noted that it is a requirement during the exception period that the Company provides prompt notification to the Panel of any significant events that occur during this time that may affect the Company's compliance with Nasdaq's requirements. This includes, but is not limited to, any event that may call into question the Company's ability to meet the terms of the exception granted. The Panel reserved the right to reconsider the terms of its decision based on any event, condition or circumstance that exists or develops that would, in the opinion of the Panel, make continued listing of the Company's securities on The Nasdaq Capital Market inadvisable or unwarranted.

The Company continues to seek additional capital from financing alternatives and other sources in order to ensure adequate funding is available to allow the Company to continue research and product development and other operating activities at their current levels. If sufficient capital is not raised, the Company will at a minimum need to significantly reduce or curtail its research and development and other operations, and this would negatively affect its ability to achieve corporate growth goals.

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

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

#### **4. Fair Value Measurements**

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

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

Money market funds are valued at the closing price reported by the fund sponsor from an actively traded exchange. Money market funds were included in cash equivalents and U.S. Treasury bills were included in investments in the condensed consolidated balance sheets for the periods presented. The Company obtains the fair value of its Level 2 cash equivalents from third-party pricing services. The pricing services utilize industry standard valuation models whereby all significant inputs, including benchmark yields, reported trades, broker/dealer quotes, issuer spreads, bids, offers, or other market-related data, are observable.

The following table summarizes the Company's fair value hierarchy for its financial assets measured at fair value on a recurring basis as of September 30, 2024 and December 31, 2023, respectively (in thousands).

September 30, 2024	Fair Value Measurements Using			
	Fair Value	Level 1	Level 2	Level 3
Money market	\$ 1,196	\$ 1,196	\$ —	\$ —
Treasury bills and government agency bonds	3,565	—	3,565	—
	<u>\$ 4,761</u>	<u>\$ 1,196</u>	<u>\$ 3,565</u>	<u>\$ —</u>

December 31, 2023	Fair Value Measurements Using			
	Fair Value	Level 1	Level 2	Level 3
Money market	\$ 5,449	\$ 5,449	\$ —	\$ —

During the nine months ended September 30, 2024, the Company issued common stock warrants which were initially classified as liabilities under authoritative accounting standards, and reclassified in the equity section of the balance sheet upon modification in August 2024 (See Note 12, Stockholders' Deficit - May 2024 Private Placement, for further details). These common stock warrants were valued using the Black Scholes model, with level 3 inputs such as expected volatility, risk-free interest rate, and expected term that are not observable in active markets.

The table below summarizes key inputs used in the valuation of the liability classified warrants as of the issuance date and as of the date of amendment:

	As of issuance date	As of date of amendment
Expected term	1.1 - 5.0 years	0.9 - 4.7 years
Common stock market price	\$2.01 - \$2.27	\$ 1.45
Risk-free interest rate	4.5% - 5.1%	3.81% - 4.63%
Expected volatility	117.0% - 127.2%	92.2% - 99.79%

The table below provides a summary of the fair value of the Company's warrant liability during the nine months ended September 30, 2024 (in thousands). As of September 30, 2023, the fair value of liability classified warrants was immaterial, and the change in the fair value of liability classified warrants during the three and nine months ended September 30, 2023 was immaterial.

	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2024
<b>Warrant liability</b>		
Beginning balance	\$ 6,160	\$ —
Issuance of warrants	—	10,854
Change in fair value of warrants	(960)	(5,654)
Reclassification to equity	(5,200)	(5,200)
Ending balance	<u>\$ —</u>	<u>\$ —</u>

## 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.

Pursuant to the Loan and Security Agreement, as amended, the Company made interest only payments through May 1, 2021, and thereafter was 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. On June 3, 2024, the Company paid off the Term Loan by making a final payment in an aggregate amount equal to approximately \$3.3 million, which included both the balance of outstanding principal and interest and the final payment fee due. The repayment in full of the Term Loan terminated Oxford's security interest in the Company's existing and after-acquired assets, as well as all other certain restrictions and covenants under the Term Loan.

## 6. Line of Credit Facility

On May 31, 2024, the Company drew down \$3.3 million on a new margin loan facility under a line of credit (the "Pershing Credit Facility") with Pershing LLC ("Pershing"), an affiliate of The Bank of New York Mellon Corporation. The available credit line limit under the Pershing Credit Facility fluctuates based on the Company's request for extensions from time to time, subject to the value of the collateralized marketable securities the Company holds with Pershing, provided that the amount available to draw under the Pershing Credit Facility cannot exceed 91.5% of the value of the collateralized marketable securities deposited with Pershing. Depending on the value of the marketable securities the Company holds with Pershing, Pershing may require the

Company from time-to-time to deposit additional funds or marketable securities in order to restore the level of collateral to an acceptable level. The amounts borrowed under the Pershing Credit Facility are due on demand. As of September 30, 2024, the Company held collateralized marketable securities with Pershing with a total value of \$3.6 million.

Borrowings under the Pershing Credit Facility bear interest at the target interest rate set by the Federal Open Market Committee, subject to a floor of 5.5%, plus a spread of 1.75% and applicable fees of 0.5%, subject to a maximum interest rate of the then applicable Prime Rate as published in The Wall Street Journal plus 3.0%. Interest payments thereunder are calculated on a monthly basis and, unless paid, are added to the outstanding balance under the Pershing Credit Facility. The proceeds under the Pershing Credit Facility are available for working capital needs and other general corporate purposes. Volatility in the global markets could cause the interest rate to fluctuate from time to time increasing the Company's costs, or could cause Pershing to terminate the Company's ability to borrow funds. In addition, borrowings under the Pershing Credit Facility have the effect of limiting the Company's use of cash and marketable securities.

## 7. 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 shares of common stock 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 shares of common stock outstanding during the period increased to include, if dilutive, the number of additional shares of common stock 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 Company considers Series A Warrants and Series B Warrants issued in connection with the private placement completed in May 2024 (See Note 12, Stockholders' Deficit - May 2024 Private Placement, for further details) to be participating securities because holders of such instruments participate in the event a dividend is paid on shares of common stock. The holders of the Series A Warrants and Series B Warrants do not have a contractual obligation to share in the Company's losses. As such, losses are attributed entirely to common stockholders and for periods in which the Company has reported a net loss.

As of September 30, 2024, 979,715 Pre-Funded Warrants to purchase shares of common stock, issued in connection with the May 2024 Private Placement (See Note 12, Stockholders' Deficit - May 2024 Private Placement, for further details), were included in the basic and diluted net loss per share calculation.

The following table sets forth the computation of basic and diluted net loss per share of common stock for the periods indicated, in thousands except share and per share data:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Basic and diluted net loss per share of common stock calculation:				
Net loss	\$ (2,874)	\$ (3,219)	\$ (9,075)	\$ (9,506)
Change in fair value of warrants	—	—	(5,047)	—
Net loss attributable to common stockholders - diluted	\$ (2,874)	\$ (3,219)	\$ (14,122)	\$ (9,506)
Weighted average shares of common stock outstanding - basic	7,855,763	3,225,351	6,232,123	2,688,232
Net loss per share of common stock - basic	\$ (0.37)	\$ (1.00)	\$ (1.46)	\$ (3.54)
Weighted average shares of common stock - diluted	7,855,763	3,225,351	8,452,338	2,688,232
Net loss per share of common stock - diluted	\$ (0.37)	\$ (1.00)	\$ (1.67)	\$ (3.54)

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

	As of September 30,	
	2024	2023
Outstanding stock options	598,540	141,077
Preferred stock	28,190	28,190
Outstanding warrants	706,674	142,733
Total	1,333,404	312,000

## 8. Biocept Asset Acquisitions

On April 26, 2024, the Company, after having its bid accepted by the United States Bankruptcy Court for the District of Delaware, acquired from Biocept, for a total cash payment of \$400,000, substantially all of the right, title and interest in a cerebrospinal fluid cancer diagnostic portfolio (“CNSide<sup>®</sup>”), including (i) intellectual property, (ii) inventory and raw materials, and (iii) data, information, results and reports pertaining to the completed and on-going clinical studies involving the use of CNSide<sup>®</sup> (including, but not limited to, the FORESEE clinical study that was being conducted by Biocept), related to the development, making, selling, and exporting or importing of the CNSide<sup>®</sup> proprietary cell enumeration test (the “CNSide Test”).

The Company concluded that the acquisition of the Biocept assets was not a business combination, as Biocept did not meet the definition of a business in ASC 805, Business Combination. The Company accounted for the asset purchase transaction under the authoritative guidance for asset acquisitions, and allocated the costs of acquisitions of approximately \$45,000 among the assets acquired based on the relative fair value of such assets, which is predominately concentrated in the intellectual property acquired including patents and trademarks. The intangible assets acquired from Biocept are capitalized and amortized over a useful life of four years.

## 9. Grant Revenue

### *CPRIT Grant*

On September 19, 2022, the Company entered into that certain Cancer Research Grant Contract (the “CPRIT Contract”), effective as of August 31, 2022, with the Cancer Prevention and Research Institute of Texas (“CPRIT”), pursuant to which CPRIT provides the Company with a CPRIT grant (“CPRIT Grant”) over a three-year period to fund the continued development of rhenium (<sup>186</sup>Re) obisbameda for the treatment of patients with leptomeningeal metastases. The CPRIT Grant is subject to customary CPRIT funding conditions, including, but not limited to, a matching fund requirement (one dollar for every two dollars awarded by CPRIT), revenue sharing obligations upon commercialization of rhenium (<sup>186</sup>Re) obisbameda based on specific dollar thresholds and tiered low single digit royalty rates until CPRIT receives the aggregate amount of 400% of the proceeds awarded under the CPRIT Grant, and certain reporting requirements.

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

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

The Company recognized \$1.5 million and \$4.4 million, and \$1.2 million and \$3.6 million in grant revenue from the CPRIT Contract during the three and nine months ended September 30, 2024 and 2023, respectively.

### *Department of Defense Award*

Effective September 1, 2024, the Company entered into an agreement with the Department of Defense office of the Congressionally Directed Medical Research Programs to receive a \$3.0 million award for research and development purposes (“DoD Award”) over a three year period. The DoD Award will be used to support the planned expansion of the Company’s clinical trial for pediatric brain cancer. The Company expects that the work performed under the DoD Award and funding of the award to commence during the fourth quarter of 2024. As of September 30, 2024, no grant revenue has been recognized related to the DoD Award. On October 4, 2024, the Company received its first payment under the DoD Award in the amount of \$0.9 million.

## 10. Commitments and Contingencies

### *Leases*

The Company leases laboratory, office and storage facilities in San Antonio, Texas, under operating lease agreements that expire in 2025. The Company also leases certain office space in Austin, Texas under a month-to-month operating lease agreement and

certain office space in Charlottesville, Virginia (the “Charlottesville Lease”). The Charlottesville Lease has a term of 12 months and the Company has the ability to renew for three additional one-year periods. On March 31, 2023, Company believed that it was reasonably certain that the Charlottesville Lease will be renewed through March 31, 2026, and as a result, it remeasured the related lease liability as of March 31, 2023 to be \$80,000 using the then-in-effect discount rate of 12.76%. Effective July 1, 2023, the Company added additional office lease premises in Charlottesville, which was accounted for as a separate operating lease contract with a lease liability and corresponding right-of-use asset of \$19,000, as a discount rate of 13.47%.

#### *Other commitments and contingencies*

The Company has entered into agreements with various research organizations for pre-clinical and clinical development studies, which have provisions for cancellation. Under the terms of these agreements, the vendors provide a variety of services including conducting research, recruiting and enrolling patients, monitoring studies and data analysis. Payments under these agreements typically include fees for services and reimbursement of expenses. The timing of payments due under these agreements is estimated based on current study progress. As of September 30, 2024, the Company did not have any clinical research study obligations.

#### *Legal proceedings*

From time to time, the Company is subject to legal proceedings and claims, whether asserted or unasserted, that arise in the ordinary course of business. 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.

## **11. License Agreements**

#### *Biocept License Agreement*

On September 7, 2023, the Company entered into a Non-Exclusive License and Services Agreement with Biocept, pursuant to which Biocept granted the Company a non-exclusive license to use the CNSide Test. In exchange for the license, the Company issued to Biocept 53,381 unregistered shares of common stock, the fair value of which was \$75,000.

On October 16, 2023, Biocept filed a voluntary petition for relief under the provisions of Chapter 7 of Title 11 of the United States Bankruptcy Code. See Note 8, the Biocept Asset Acquisitions, for further details.

#### *University of Texas Health Science Center at San Antonio (“UTHSCSA”) License Agreement*

On December 31, 2021, the Company entered into a Patent and Know-How License Agreement with UTHSCSA, pursuant to which UTHSCSA granted the Company an irrevocable, perpetual, exclusive, fully paid-up license, with the right to sublicense and to make, develop, commercialize and otherwise exploit certain patents, know-how and technology related to the development of biodegradable alginate microspheres containing nanoliposomes loaded with imaging and/or therapeutic payloads.

#### *NanoTx License Agreement*

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

The transaction terms included an upfront payment of \$0.4 million in cash and \$0.3 million in the Company’s shares of common stock. The transaction terms also included success-based milestone and royalty payments contingent on key clinical, regulatory and sales milestones, as well as the requirement to pay 15% of any non-dilutive monetary awards or grants received from external agencies to support product development of the nanoliposome encapsulated BMEDA-chelated radioisotope, which includes grants from CPRIT. As of September 30, 2024, the Company accrued \$1.0 million of payments due to NanoTx as a result of the CPRIT grant received (see Note 9, Grant Revenue, for further details).

## **12. Stockholders’ Deficit**

### **Preferred Stock**

The Company has authorized 5,000,000 shares of preferred stock, par value \$0.001 per share. The Company’s Board is authorized to designate the terms and conditions of any preferred stock the Company issues without further action by the common stockholders.

#### *Series F Preferred Stock*

On March 3, 2023, the Company filed a certificate of designation (the “Certificate of Designation”) with the Secretary of State of the State of Delaware, effective as of the time of filing, designating the rights, preferences, privileges and restrictions of the Series F Preferred Stock, with the total authorization of one (1) share of Series F Preferred Stock. The Certificate of Designation provided that the share of Series F Preferred Stock would have 50,000,000 votes per share of Series F Preferred Stock and would vote together with the Company’s common stock, as a single class exclusively with respect to any proposal to amend the Company’s certificate of incorporation to effect the reverse stock split. On March 3, 2023, the Company entered into a subscription and investment representation agreement with Richard J. Hawkins, chairman of the board of the Company, who is an accredited investor (the “Series F Preferred Stock Purchaser”), pursuant to which the Company agreed to issue and sell one (1) share of the Company’s Series F Preferred Stock, par value \$0.001 per share, to the Series F Preferred Stock Purchaser for \$1,000 in cash. The sale closed on March 3, 2023.

The outstanding share of Series F Preferred Stock was redeemed in whole, automatically effective upon the approval by the Company’s stockholders of the reverse stock split in April 2023. Upon such redemption, the Series F Preferred Stock Purchaser received consideration of \$1,000 in cash.

On November 12, 2024, the Company filed a Certificate of Elimination (“Certificate of Elimination”) with the Secretary of State of the State of Delaware effecting the elimination of the Certificate of Designation relating to the Series F Preferred Stock. Following the filing of the Certificate of Elimination the previously-authorized share of the Series F Preferred Stock resumed the status of an undesignated share of the Company’s preferred stock.

#### *Series B and C Preferred Stock*

As of September 30, 2024, there were 938 outstanding shares of Series C Preferred Stock that can be converted into an aggregate of 27,792 shares of common stock, and 1,014 shares of Series B Convertible Preferred Stock that can be converted into an aggregate of 398 shares of common stock.

### **Common Stock**

#### *May 2024 Private Placement*

On May 5, 2024, the Company entered into a securities purchase agreement (the “Securities Purchase Agreement”) with certain investors, including certain of the Company’s directors and executive officers (“Company Insiders”) (collectively, the “Purchasers”), for the sale and issuance by the Company of its securities (the “Initial Subscription”). On May 8, 2024, the Company entered into a first amendment to the Securities Purchase Agreement (together with the Securities Purchase Agreement, the “Purchase Agreement”), for the sale and issuance by the Company of additional securities to two of the Purchasers (the “Additional Subscription”, and together with the Initial Subscription, the “May 2024 Private Placement”). The Purchase Agreement provides for the sale and issuance by the Company of an aggregate of 3,591,532 shares (the “Private Placement Shares”) of the Company’s common stock or, at the election of each Purchaser, pre-funded warrants (the “Pre-Funded Warrants”), exercisable immediately at an exercise price of \$0.001 per share, with each Private Placement Share or Pre-Funded Warrant accompanied by (i) a Series A common warrant (“Series A Warrants”) to purchase one share of common stock, for an aggregate of 3,591,532 Series A Warrants, and (ii) one Series B common warrant (“Series B Warrants”) to purchase one share of common stock, for an aggregate of 3,591,532 Series B Warrants.

The combined purchase price for each Private Placement Share and Pre-Funded Warrant from the Initial Subscription was \$2.022, and \$2.158 from the Additional Subscription, in each case together with one accompanying Series A Warrant and one accompanying Series B Warrant, provided, that the Company Insiders participated in the Initial Subscription at an offering price of \$2.04 per Private Placement Share and accompanying Series A Warrant and Series B Warrant.

The exercise price of Series A Warrants and Series B Warrants from the Initial Subscription is \$1.772 per share and \$1.908 per share in the Additional Subscription, provided that the exercise price for the Series A Warrants and Series B Warrants issued to the Company Insiders is \$1.79 per share. Subject to certain ownership limitations, the Series A Warrants will be exercisable until May 9, 2029, which is the five-year anniversary of issuance. Subject to certain ownership limitations, the Series B Warrants will be exercisable until June 24, 2025. The Pre-Funded Warrant will not expire until exercised in full.

Prior to the Amendment and Restatements (as defined below), if a holder of a Series A Warrant or a Series B Warrant was unable to exercise the warrant due to the limitation contained in the warrant that restricts the holder from owning above a specified beneficial ownership level (generally 4.99% or 9.99%) as the result of exercise of the warrant, then the holder had the right to elect upon exercise of the warrant to receive a Pre-Funded Warrant for the same number of shares of common stock that would otherwise have been received upon exercise of the warrant. In addition, prior to the Amendment and Restatements, the Series A Warrants and Series B Warrants provided for a call right starting June 24, 2025, in favor of the Company, if the volume-weighted average price of the shares of common stock exceeds specified prices.

The May 2024 Private Offering closed on May 9, 2024. The Company issued 2,151,544 Pre-Funded Warrants, 3,591,532 Series A Warrants and 3,591,532 Series B Warrants to purchase shares of its common stock in connection with the May 2024 Private Placement. The aggregate gross proceeds from the May 2024 Private Placement were approximately \$7.3 million, before deducting \$0.4 million of offering expenses.

The Company reviewed the terms of the Pre-Funded Warrants, Series A Warrants and Series B Warrants under the authoritative accounting guidance as of the issuance date.

As described above, the Series A Warrants and Series B Warrants were initially classified as liabilities for the reason that they could have been exercised into either shares of common stock or Pre-Funded Warrants at the holder's option and thus failed the indexation guidance under ASC 815, Derivatives and Hedging. The Series A Warrant and Series B Warrant liability were initially recorded at fair value as of the issuance date, and under the terms of the Series A Warrants and Series B Warrants when issued that liability was subject to adjustment to estimated fair value at each balance sheet date until the warrants were settled. Refer below for additional information regarding the amendment of the Series A Warrants and Series B Warrants that eliminated the ability of the Series A Warrants and Series B Warrants to be exercised into Pre-Funded Warrants, and as a result, the reclassification of the Series A and B Warrants from liability to equity section of the condensed consolidated balance sheet.

The Pre-Funded Warrants are equity classified because they (1) are freestanding financial instruments that are legally detachable and separately exercisable from the common stock, (2) are immediately exercisable, (3) do not embody an obligation for the Company to repurchase its shares, (4) permit the holder to receive a fixed number of shares of common stock upon exercise, (5) are indexed to the Company's common stock and (6) meet the equity classification criteria.

The proceeds from the May 2024 Private Placement were first allocated to the full fair value of the Series A Warrants and Series B Warrants due to the initial liability classification. As disclosed in Note 4, Fair Value Measurements, the fair value of the Series A Warrants and Series B Warrants at issuance was \$10.9 million. Under authoritative guidance, if the fair value of a warrant liability exceeds the proceeds received in an arm's length transaction with no rights or privileges that require separate accounting recognition as an asset identified, then the warrant liability is recorded at fair value with the excess of fair value over proceeds recognized as a loss in earnings. The Company recognized approximately \$3.5 million in financing expense in the condensed consolidated statement of operations during the nine months ended September 30, 2024, which represents the excess of the fair value of the Series A Warrants and Series B Warrants at issuance over the proceeds. During the three and nine months ended September 30, 2024, the Company recognized a fair value gain on warrant liability of \$1.0 and \$5.7 million, respectively. Proceeds from the May 2024 Private Placement are shown as cash from financing transactions and the gain on warrant liability is included as an adjustment to reconcile the net loss to net cash used in operating activities in the statements of cash flows for the nine months ended September 30, 2024.

In addition, total offering expenses related to the May 2024 Private Placement of \$0.4 million were recorded as a component of other expenses as the entire proceeds were allocated to the warrant liability, which, prior to the amendment described below, could be settled with either the Company's shares of common stock or Pre-Funded Warrants, which are exercisable into the Company's shares of common stock at any time at the holders' option, but not in cash payment to the holders.

As of September 30, 2024, all of the Series A Warrants, and Series B Warrants issued in connection with the May 2024 Private Placement remained outstanding, and Pre-Funded Warrants to purchase 1,959,430 shares of the Company's common stock remained outstanding.

#### *Amendment and Restatement of Series A Warrants and Series B Warrants*

On August 9, 2024, the Company amended and restated the Series A Warrants and Series B Warrants (the "Amendment and Restatements") issued in the May 2024 Private Placement. The Amendment and Restatements eliminated the ability of the holders of the Series A Warrants and Series B Warrants to elect to purchase Pre-Funded Warrants upon exercise of the Series A Warrants and Series B Warrants in lieu of shares of common stock if the holder would have been restricted because of the specified beneficial ownership level in the Series A Warrants and Series B Warrants.

In addition, the Amendment and Restatements eliminated the Company's call right under the terms of the Series A Warrants to call the Series A Warrants after June 24, 2025, if the volume-weighted average price of shares of common stock exceeded specified prices. There were no other changes in the terms of the Series A Warrants and Series B Warrants.

As a result of the Amendment and Restatements, the Series A Warrants and Series B Warrants, as amended, no longer fail the indexation guidance under ASC 815, Derivatives and Hedging, and the fair value of the warrant liability at the amendment date, in the amount of \$5.2 million, was reclassified to equity.

#### *Lincoln Park Purchase Agreement*

On August 2, 2022, the Company entered into a purchase agreement (the “2022 Purchase Agreement”) and registration rights agreement pursuant to which Lincoln Park Capital Fund (“Lincoln Park”) committed to purchase up to \$50.0 million of the Company’s common stock. Under the terms and subject to the conditions of the 2022 Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to \$50.0 million of the Company’s common stock. Such sales of common stock by the Company are subject to certain limitations, and can occur from time to time, at the Company’s sole discretion, over the 36-month period commencing on August 17, 2022, subject to the satisfaction of certain conditions.

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

Upon execution of the 2022 Purchase Agreement, the Company paid \$0.1 million in cash as the initial commitment fee, and issued 32,846 shares as the initial commitment shares, to Lincoln Park as consideration for its irrevocable commitment to purchase shares of the Company’s common stock at its direction under the 2022 Purchase Agreement. The Company has agreed to pay an additional commitment fee, which it may elect to pay in cash or shares of its common stock, or a combination of cash and shares of its common stock, upon receipt of \$25.0 million aggregate gross proceeds from sales of common stock to Lincoln Park under the 2022 Purchase Agreement.

On August 17, 2022, a registration statement (the “First Registration Statement”) was declared effective to cover the resale of up to 633,333 shares of the Company’s common stock comprised of (i) the 32,846 initial commitment shares, and (ii) up to 600,486 that the Company has reserved for issuance and sale to Lincoln Park under the 2022 Purchase Agreement from time to time from and after the date of the prospectus. The Company sold 527,166 shares of common stock to Lincoln Park in connection with the First Registration Statement.

On August 18, 2023, a second registration statement (the “Second Registration Statement”) was declared effective to cover the resale of up to an additional 1,500,000 shares of the Company’s common stock that the Company reserved for issuance and sale to Lincoln Park under the 2022 Purchase Agreement from time to time. The Company sold 150,000 shares of common stock to Lincoln Park in connection with the Second Registration Statement. The Company cannot sell more shares than registered under the Second Registration Statement under the 2022 Purchase Agreement without registering additional shares.

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

During the period from August 17, 2022 to December 31, 2022, the Company issued 266,666 shares of common stock under the 2022 Purchase Agreement for net proceeds of approximately \$3.2 million. The Company issued 410,500 shares of common stock under the 2022 Purchase Agreement for net proceeds of approximately \$1.0 million from January 1, 2023 to December 31, 2023. The Company did not issue any shares of common stock under the 2022 Purchase Agreement during the nine months ended September 30, 2024.

#### *Share Repurchase Program and Treasury Stock*

On October 31, 2023, the Company announced that its Board has approved a share repurchase program (the “Share Repurchase Program”), with authorization to repurchase up to \$500,000 of the outstanding shares of the Company’s common stock. The Company funded repurchases under the Share Repurchase Program with available cash.

During the year ended December 31, 2023, the Company purchased 78,559 shares of its common stock for approximately \$0.1 million as treasury stock. The Company purchased 179,866 shares of its common stock for approximately \$0.4 million as treasury stock during the nine months ended September 30, 2024. As of September 30, 2024, no amount remained authorized for repurchase.

### **13. Stock-based Compensation**

Under the Company’s 2015 New Employee Incentive Plan, as amended (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. On June 6, 2024, the Company’s Board increased the number of shares for future issuances under the 2015 Plan by 75,000 shares of common stock. As of September 30, 2024, there were 62,908 shares of common stock remaining and available for future issuances under the 2015 Plan.

The Company’s 2020 Stock Incentive Plan, as amended and restated (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 provides for the issuance of up to 1,236,667 shares of common stock, including an increase of 1,000,000 shares as approved by the Company’s stockholders at the Company’s 2024 annual stockholders’ meeting during the three months ended September 30, 2024, plus the number of shares of common stock available for issuance is increased to the extent that awards granted under the 2020 Plan and the Company’s 2014 Equity Incentive Plan are forfeited or expire (except as otherwise provided in the 2020 Plan). As of September 30, 2024, there were 692,596 shares remaining and available for future issuances under the 2020 Plan.

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

A summary of activity for the nine months ended September 30, 2024 is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance as of December 31, 2023	140,109	\$ 37.48	8.07	
Granted	506,127	\$ 1.58		
Cancelled/expired	(47,696)	\$ 38.02		
Balance as of September 30, 2024	<u>598,540</u>	<u>\$ 7.08</u>	<u>9.25</u>	<u>\$ 64,000</u>
Vested and expected to vest at September 30, 2024	<u>540,286</u>	<u>\$ 7.60</u>	<u>7.37</u>	<u>\$ —</u>
Exercisable at September 30, 2024	<u>110,674</u>	<u>\$ 28.73</u>	<u>9.20</u>	<u>\$ 56,000</u>

As of September 30, 2024, the total compensation cost related to non-vested stock options not yet recognized for all the Company’s plans is approximately \$0.8 million, which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 2.8 years.

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

*The following discussion and analysis should be read in conjunction with the unaudited financial information and the notes thereto included herein, as well as the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our audited financial statements and notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2023, as filed on March 5, 2024. 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 quarterly report on Form 10-Q, as well as under “Part I – Item 1A - Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2023, in other subsequent filings with the Securities and Exchange Commission, and elsewhere in this quarterly report on Form 10-Q. These statements, like all statements in this quarterly report on Form 10-Q, speak only as of the date of this quarterly report on Form 10-Q (unless another date is indicated), and the Company undertakes no obligation to update or revise these statements in light of future developments.*

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

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

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

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

### Overview

Plus Therapeutics is a U.S. pharmaceutical company developing targeted radiotherapeutics with advanced platform technologies for central nervous system (“CNS”) cancers. Our novel radioactive drug formulations and medical devices and therapeutic candidates are designed to deliver safe and effective doses of radiation to tumors. To achieve this, we have developed innovative approaches to drug formulation, including encapsulating radionuclides such as rhenium isotopes with nanoliposomes and microspheres. Our formulations are intended to achieve elevated patient absorbed radiation doses and extend retention times such that the clearance of the isotope occurs after significant and essentially complete radiation decay, which will contribute and provide less normal tissue/organ exposure and improved safety margins.

Traditional approaches to radiation therapy for cancer, such as external beam radiation, have many disadvantages including continuous treatment for four to six weeks (which is onerous for patients), that the radiation damages healthy cells and tissue, and that the amount of radiation delivered is very limited and, therefore, is frequently inadequate to fully destroy the cancer.

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

Our lead radiotherapeutic candidate, rhenium (<sup>186</sup>Re) obisbameda, is designed specifically for CNS cancers including recurrent glioblastoma (“GBM”), leptomeningeal metastases (“LM”), and pediatric brain cancers (“PBC”) by direct localized delivery utilizing approved standard-of-care tissue access such as with convection-enhanced delivery (“CED”) and intraventricular brain (Ommaya reservoir) catheters. Our 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.

On April 26, 2024, we acquired all of the right, title and interest in a cerebrospinal fluid cancer diagnostic portfolio (“CNSide<sup>®</sup>”) from Biocept that is currently utilized in the CPRIT-funded ReSPECT-LM clinical trial. In August 2024, data from the CNSide FORESEE clinical trial in patients with leptomeningeal metastases (LM) was presented at the SNO/ASCO CNS Metastases Conference. The trial met its key primary and secondary endpoints and the data showed that CNSide<sup>®</sup> more than doubled the diagnostic sensitivity versus gold standard cerebrospinal fluid cytology and influenced clinical management decisions in over 90% of LM cases. We are currently evaluating and developing our business plan for developing the CNSide<sup>®</sup> diagnostic portfolio alongside our lead radiotherapeutic candidate, rhenium (<sup>186</sup>Re) obisbameda, and seeking partnering opportunities for CNSide<sup>®</sup>. The CNSide<sup>®</sup> proprietary cell enumeration test (the “CNSide Test”) is on track for commercial launch as soon as the fourth quarter of 2024.

We are headquartered in Austin, Texas, in proximity to world-class cancer institutions and researchers. Our dedicated team of engineers, physicians, scientists, and other professionals are committed to advancing our targeted radiotherapeutic technology for the benefit of

cancer patients and healthcare providers worldwide and our current pipeline is focused on treating rare and difficult-to-treat cancers with significant unmet medical needs.

In addition to our headquarters in Austin, we have an established, good manufacturing practice validated research and development and manufacturing facility in San Antonio, Texas, tailored to produce Current Good Manufacturing Practice (“cGMP”) rhenium (<sup>186</sup>Re) obisbameda. We recently expanded our manufacturing capabilities by entering into a services agreement for the radiotherapeutic development and production in a manufacturing facility in Indiana. We have built a robust supply chain through strategic partnerships that enable the development, manufacturing and future potential commercialization of our products. Our current supply chain and key partners are positioned to supply cGMP rhenium (<sup>186</sup>Re) obisbameda for ongoing and planned Phase 2 and Phase 3 clinical trials in patients with GBM, LM and PBC.

## Pipeline

Our most advanced investigational drug, rhenium (<sup>186</sup>Re) obisbameda, is a patented radiotherapy potentially useful for patients with CNS and other cancers. Preclinical study data describing the use of rhenium (<sup>186</sup>Re) obisbameda for several cancer targets have been published in peer-reviewed journals and reported at a variety of medical society peer-reviewed meetings. Besides GBM, LM and PBC, rhenium (<sup>186</sup>Re) obisbameda has been reported to have potential applications for head and neck cancer, ovarian cancer, breast cancer and peritoneal metastases.

The rhenium (<sup>186</sup>Re) obisbameda 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 is expected to provide financial support for the continued clinical development of rhenium (<sup>186</sup>Re) obisbameda for recurrent GBM through the completion of a Phase 2 clinical trial, including enrollment of up to 55 patients.

On August 29, 2022, we announced feedback from a Type C meeting with the U.S. Food and Drug Administration (“FDA”) regarding Chemistry, Manufacturing and Controls practices. The meeting focused on our cGMP clinical and commercial manufacturing process for our lead investigational targeted radiotherapeutic, BMEDA-chelated rhenium (<sup>186</sup>Re) obisbameda, for recurrent GBM.

The FDA indicated agreement with our proposed application of cGMP guidance for radiotherapeutics, small molecule drug products and liposome drug products for our novel rhenium (<sup>186</sup>Re) obisbameda in support of ongoing and future GBM clinical trials, manufacturing scale up, and commercialization. Alignment with the FDA includes support of our proposed controls and release strategy for new drug substance and new drug product. Because this product is identical for recurrent GBM, LM, and PBC, we believe alignment will be consistent for rhenium (<sup>186</sup>Re) obisbameda used in other clinical development programs, including LM and PBC.

### *Rhenium (<sup>186</sup>Re) obisbameda versus External Beam Radiation Therapy for Recurrent GBM*

Rhenium (<sup>186</sup>Re) obisbameda is a novel injectable radiotherapy designed to deliver targeted, high dose radiation directly into GBM tumors in a safe, effective, and convenient manner that may ultimately prolong patient survival. Rhenium (<sup>186</sup>Re) obisbameda is composed of the radionuclide Rhenium-186 and a nanoliposomal carrier, and is infused in a highly targeted, controlled fashion, directly into the tumor via precision brain mapping and CED catheters. Potential benefits of rhenium (<sup>186</sup>Re) obisbameda compared to standard external beam radiotherapy or external beam radiation therapy (“EBRT”) include:

- The rhenium (<sup>186</sup>Re) obisbameda radiation dose delivered to patients may be up to 20 times greater than what is possible with commonly used EBRT, which, unlike EBRT and proton beam devices, spares normal tissue and the brain from radiation exposure.
- Rhenium (<sup>186</sup>Re) obisbameda can be visualized in real-time during administration, possibly giving clinicians better control of radiation dosing, distribution and retention.
- Rhenium (<sup>186</sup>Re) obisbameda potentially more effectively treats a bulk tumor and microscopic disease that has already invaded healthy tissue.
- Rhenium (<sup>186</sup>Re) obisbameda is infused directly into the targeted tumor by CED catheter insertion using MRI guided software to avoid critical patient neurological structures and neural pathways and also bypasses the blood brain barrier, which delivers the therapeutic product where it is needed. Importantly, it reduces radiation exposure to healthy cells, in contrast to EBRT, which passes through normal tissue to reach the tumor, continuing its path through the tumor, hence being less targeted and selective.

- Rhenium ( $^{186}\text{Re}$ ) obisbameda is given during a single, short, in-patient hospital visit, and is available in all hospitals with nuclear medicine and neurosurgery, while EBRT requires out-patient visits five days a week for approximately four to six weeks.

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

GBM affects approximately 15,000 patients annually in the U.S. and is the most common and lethal form of brain cancer. The average life expectancy with GBM is less than 24 months, with a one-year survival rate of 40% and a five-year survival rate of around 5%. There is no clear standard of care for recurrent GBM and the few currently approved treatments provide only marginal survival benefit and are associated with significant side effects, which limit dosing and prolonged use. Approximately 90% of patients experience GBM tumor recurrence at or near the original tumor location, yet there are no FDA-approved treatments in the recurrent or progressive setting that can significantly extend a patient's life. GBM routinely presents with headaches, seizures, vision changes and other significant neurological complications, with a significant compromise in quality of life. Despite the best available medical treatments, the disease remains incurable. Even after efforts to manage the presenting signs and symptoms and completely resect the initial brain tumor, some microscopic disease almost always remains and tumor regrowth occurs within months. Complete surgical removal of GBM is usually not possible and GBM is often resistant or quickly develops resistance to most available current and investigational therapies. Even today, the treatment of GBM remains a significant challenge and it has been nearly a decade since the FDA approved a new therapy for this disease, and these more recent approvals have not improved GBM patients OS over past decades, and a significant unmet medical need persists.

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

While EBRT has been shown to be safe and has temporary efficacy in many malignancies including GBM, typically at absorbed, fractionated radiation dose of ~30 Gray in GBM, this maximum possible administered dose is always limited by toxicity to the normal tissues surrounding the malignancy and because EBRT requires fractionation to manage toxicity and maximum EBRT limits are typically reached before long-term efficacy reached. Because of this limitation, EBRT cannot provide a cure or long term control of GBM and GBM always recurs within months after EBRT. In contrast, locally delivered and targeted radiopharmaceuticals that precisely deliver radiation in the form of beta particles such as Iodine-131 for thyroid cancer, are known to be safe and effective and minimize exposure to normal cells and tissues especially with optimal administered dose and minimizing exposure to normal tissue. The locally delivered rhenium ( $^{186}\text{Re}$ ) obisbameda is designed for and provides patient tolerability and safety. Though no rhenium ( $^{186}\text{Re}$ ) obisbameda head-to-head trial with chemo, immune, EBRT or systemic radiopharmaceutical products have been conducted, patient tolerability and safety considerations have been reported as expected.

Interim results from our ongoing Phase 1/2a ReSPECT-GBM trial (ClinicalTrials.gov NCT01906385) show that the beta particle energy from our lead investigational drug rhenium ( $^{186}\text{Re}$ ) obisbameda has provided preliminary positive data and utility in treating GBM and potential other malignancies. More specifically, the preliminary data from our Phase 1/2a ReSPECT-GBM trial suggests that radiation, in the form of high energy beta particles or electrons, can be effective against GBM. Thus far, we have been able to deliver up to 740 Gy of absorbed radiation to tumor tissue in humans, without significant or dose limiting toxicities and with what we believe has the capability to go higher if required. In comparison, current EBRT protocols for recurrent GBM typically recommend a total maximum radiation dose of about ~30-35 Gray.

In September 2020, the FDA granted both Orphan Drug designation and Fast Track designations to rhenium ( $^{186}\text{Re}$ ) obisbameda for the treatment of patients with GBM.

Rhenium ( $^{186}\text{Re}$ ) obisbameda is under clinical investigation in a multicenter, sequential cohort, open-label, volume and dose escalation study of the safety, tolerability, and distribution of rhenium ( $^{186}\text{Re}$ ) obisbameda given by CED catheters to patients with recurrent or progressive malignant glioma after standard surgical, radiation, and/or chemotherapy treatment (NCT01906385). The study uses a standard, modified 3x3 Fibonacci dose escalation, followed by a planned Phase 2 expansion trial at the maximum tolerated dose ("MTD") / maximum feasible dose ("MFD") or non-dose limiting toxicity ("DLT") if MTD is not reached, to determine efficacy. The trial is funded through Phase 2 in large part by a National Institute of Health/National Cancer Institute ("NIH/NCI") grant. These investigations have not reached DLT or MTD/MFD and the study is in its eighth dosing administration cohort. Due to the observation of a preliminary efficacy signal, we have initiated in parallel a Phase 2, non-DLT dose trial pursuant to the currently funded NIH/NCI grant. This trial will begin at the current non-DLT rhenium ( $^{186}\text{Re}$ ) obisbameda dose and will expand exploring higher radiation doses in larger volumes to treat larger tumors. Additionally, two or more rhenium ( $^{186}\text{Re}$ ) obisbameda administrations, if indicated, will be evaluated, and reviewed with the FDA, as well as expanded safety, imaging and efficacy data to support a planned future registrational trial.

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

On January 18, 2023, we announced that the first patient was dosed in the ReSPECT-GBM Phase 2b dose expansion clinical trial evaluating rhenium obisbameda for the treatment of recurrent GBM. The Phase 2b trial is expected to enroll up to 34 total patients with small- to medium-sized tumors and is targeted for full enrollment by the end of 2024. We currently have five clinical sites, and expect an initial data read-out by the end of 2024.

In June 2023, we presented data regarding the safety and feasibility results from our Phase 1/2 Clinical Trial of <sup>186</sup>RNL (Rhenium-186 Nanoliposome) (<sup>186</sup>Re) Obisbameda in Recurrent Glioma: The ReSPECT-GBM Trial at the Society of Nuclear Medicine & Molecular Imaging Annual Meeting.

On November 20, 2023, we announced positive data from the ongoing ReSPECT-GBM Phase 2 trial evaluating rhenium (<sup>186</sup>Re) obisbameda, for the treatment of recurrent glioblastoma at the Society for NeuroOncology 28th Annual Meeting, which was held November 15-19, 2023 in Vancouver, Canada. Key findings included:

- Median overall survival (mOS) in 15 patients with recurrent glioblastoma (“rGBM”) from the Phase 2 study is 13 months, which is 63% better than current standard of care (bevacizumab monotherapy) of 8 months; 9 of the 15 patients remain alive.
- Median progression free survival (mPFS) is 11 months, compared to SOC at 4 months.
- Rhenium (<sup>186</sup>Re) obisbameda continues to demonstrate a favorable safety profile, despite delivering up to 20x the dose of radiation (up to 740 Gy) typically delivered by EBRT for rGBM patients (up to 35 Gy).
- Imaging data presented by Andrew Brenner, MD, PhD is consistent with the efficacy signal of Rhenium (<sup>186</sup>Re) obisbameda in rGBM.

On September 30, 2024, we showcased new interim ReSPECT-GBM Phase 2 Trial Data at the 2024 Congress of Neurological Surgeons Annual Meeting that included:

- 42 total patients have enrolled thus far at 3 sites and with 19/42 patients having been treated to date at the recommended Phase 2 dose (22.3 mCi in 8.8 mL) in tumors of approximately 20 cm<sup>3</sup> or less
- All Phase 2 patients have recurrent, histologically confirmed glioblastoma; 1 recurrence, bevacizumab naïve, single tumor of approximately 20 cm<sup>3</sup> or less (small-to-medium sized tumors)
- Average tumor size in Phase 2 was 7.5 mL (range 0.9-22.8 mL)
- Increases in absorbed dose correlated with specific drug delivery parameters such as infused dose and volume, maximal convection flow rate, and number of catheters
- Rhenium (<sup>186</sup>Re) Obisbameda continues to show a favorable safety profile in the 42 enrolled patients; one dose-limiting toxicity (hemiplegia) has been reported, which was observed in Cohort 8 (41.5 mCi and 16.3 mL)
- In Phase 2, most adverse events (AEs) were mild (73.5%) or moderate (18.8%), and largely unrelated (37.7%), or unlikely related (27.1%) to the drug. Of the 9 severe adverse events (SAEs), only 2 were related to the study drug
- Average absorbed radiation dose to the tumor in Phase 2 was 300 Gy (n=18, 1 patient still under analysis)
- To date, 88.9% of Phase 2 patients met key CED drug delivery parameters shown to correlate with overall survival, achieving a tumor absorbed dose >100 Gy and radiation coverage of >70%
- 29/42 patients treated thus far participated in the Phase 1 dose escalation phase of the trial (Note: as per protocol, 6/42 patients were included in both the Phase 1 and Phase 2 trial arms and related analyses)
- Phase 1 dose-escalation increased administered doses from 1.0 mCi to 41.5 mCi and volumes from 0.66 mL to 16.3 mL

- In terms of objective tumor response based on quantitative image analysis, a statistically significant reduction in tumor volume rate change was seen in tumors receiving > 100 Gy absorbed dose (n=11 patients analyzed to date, p<0.005). Sufficient tumor coverage correlated with tumor control, while regrowth occurred outside treated areas

We anticipate completing our Phase 1 ReSPECT-GBM Trial for large sized tumors in mid-2025 and completing our Phase 2 ReSPECT-Recurrent GBM Trial in mid-2025 as well.

#### *ReSPECT-LM Clinical Trials for LM*

LM is a rare complication of cancer in which the disease spreads to the membranes (meninges) surrounding the brain and spinal cord. The incidence of LM is growing and occurs in approximately 5%, or more, of people with late-stage cancer, or 110,000 people in the U.S. each year. It is highly lethal with an average one-year survival of just 7%. All solid cancers, particularly breast, lung, GI, and melanoma, have the potential to spread to the leptomeninges.

The ReSPECT-LM Phase 1 clinical trial (ClinicalTrials.gov NCT05034497) was preceded with preclinical studies in which tolerance to doses of rhenium (<sup>186</sup>Re) obisbameda as high as 1,075 Gy were shown in animal models with LM without significant observed toxicity. Furthermore, treatment led to a marked reduction in tumor burden in both C6 and MDA-231 LM models.

Upon receiving acceptance of our Investigational New Drug application and Fast Track designation by the FDA for rhenium (<sup>186</sup>Re) obisbameda for the treatment of LM in November 2021, we initiated the trial and began screening patients for the ReSPECT-LM Phase 1 clinical trial in the fourth quarter of 2021.

ReSPECT-LM is a multi-center, sequential cohort, open-label, dose escalation study evaluating the safety, tolerability, and efficacy of a single-dose application of rhenium (<sup>186</sup>Re) obisbameda administered through intrathecal infusion to the ventricle of patients with LM after standard surgical, radiation, and/or chemotherapy treatment. The primary endpoint of the study is the incidence and severity of adverse events and dose limiting toxicities, together with determining the maximum tolerated and recommended Phase 2 dose. Full enrollment in the Phase 1 trial is expected by the end of 2024, with the plan to add additional clinical sites to support the trial.

On September 19, 2022, we entered into a Cancer Research Grant Contract (the “CPRIT Contract”), effective as of August 31, 2022, with Cancer Prevention and Research Institute of Texas (“CPRIT”), pursuant to which CPRIT will provide us a grant of up to \$17.6 million (the “CPRIT Grant”) over a three-year period to fund the continued development of rhenium (<sup>186</sup>Re) obisbameda for the treatment of patients with LM through Phase 2 of the ReSPECT LM clinical trial. The CPRIT Grant is subject to customary CPRIT funding conditions, including, but not limited to, a matching fund requirement (one dollar from us for every two dollars awarded by CPRIT), revenue sharing obligations upon commercialization of rhenium (<sup>186</sup>Re) obisbameda based on specific dollar thresholds until CPRIT receives the aggregate amount of 400% of the proceeds awarded under the CPRIT Grant, and certain reporting requirements. To date, we have received approximately \$10.7 million in milestone payments under the CPRIT Contract.

Interim results showed that a single treatment with rhenium (<sup>186</sup>Re) obisbameda resulted in a consistent decreased cerebrospinal fluid (“CSF”) tumor cell count/ml and was tolerated by all LM patients. Rhenium (<sup>186</sup>Re) obisbameda is an outpatient administration and treatment and is easily and safely administered through a standard intraventricular catheter (Ommaya Reservoir), distributed promptly throughout the CSF, and with durable retention in the leptomeninges at least through day seven. All patients have shown well tolerated prompt and durable rhenium (<sup>186</sup>Re) obisbameda distribution throughout the subarachnoid space. On March 11, 2024, we announced we had completed Cohort 5 of the ReSPECT-LM Phase 1/2a dose escalation trial.

A total of 26 patients have received a single-dose of rhenium (<sup>186</sup>Re) obisbameda in the ReSPECT-LM trial as of October 9, 2024. There have been no dose limiting toxicities observed to date with administered radiation doses up to 66.14 millicuries in Cohort 5, a ten-fold increase over Cohort 1. In addition, five new clinical trial sites were added to this trial over the last year, bringing the total number of sites to seven.

On August 10, 2023, we presented data from the ReSPECT-LM clinical trial of rhenium (<sup>186</sup>Re) obisbameda at the Society for Neuro Oncology ASCO CNS Cancer Conference.

In November 2023, the FDA granted Orphan Drug designation to rhenium (<sup>186</sup>Re) obisbameda for the treatment of patients with breast cancer with LM.

On December 12, 2023, we announced our partnership with K2bio to implement novel analysis for CSF tumor and molecular biomarkers for CNS cancers. Initial clinical specimen processing and testing began in the first quarter 2024 in our ongoing Phase 1 ReSPECT-LM trial of rhenium (<sup>186</sup>Re) obisbameda in patients with LM.

In mid-June 2024, we presented updated data from our Phase 1 ReSPECT-LM trial at the annual meeting of Society of Nuclear Medicine & Molecular Imaging (SNMMI) conference.

From August 8-10, 2024, we presented data at the 2024 Society for NeuroOncology (SNO)/American Society for Clinical Oncology (ASCO) CNS Metastases Conference. The presentation, titled, “Phase 1 Dose Escalation of Rhenium (<sup>186</sup>Re) Obisbameda (Rhenium Nanoliposome, <sup>186</sup>RNL) for the Treatment of Leptomeningeal Metastases (LM): Ongoing Clinical Study Update for Initial Safety and Feasibility,” provided a safety and efficacy update on the single dose trial for the first 4 cohorts (n = 16 patients). The trial is currently enrolling in Cohort 5. The study was presented by Andrew Brenner, M.D., Ph.D., Professor and Koltitz/Zachry Endowed Chair Neuro-Oncology Research; Co-Leader, Experimental and Developmental Therapeutics Program, University of Texas Health, San Antonio.

We anticipate completing the Phase 1 single administration ReSPECT-LM trial this year and intend to present data at the Society for Neuro-Oncology conference in November 2024. We also anticipate beginning enrollment for a ReSPECT-LM Multi-Dose trial in the first quarter of 2025.

#### *ReSPECT-PBC Clinical Trial for Pediatric Brain Cancer*

The average annual age adjusted mortality rate for children aged 0-14 for malignant brain (and other CNS) tumors is 0.71/100,000, making it the most common cause of death and cancer death in this age group. The 2021 World Health Organization Classification of CNS Tumors classifies gliomas, glioneuronal tumors, and neuronal tumors into six different families: (1) adult-type diffuse gliomas; (2) pediatric-type diffuse low-grade gliomas; (3) pediatric-type diffuse high-grade gliomas (“HGG”); (4) circumscribed astrocytic gliomas; (5) glioneuronal and neuronal tumors; and (6) ependymomas.

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

Given the initial FDA feedback, receipt of adult GBM data and experience with rhenium (<sup>186</sup>Re) obisbameda and follow-up communications with the FDA, we plan to submit a pediatric brain tumor IND for our ReSPECT-PBC clinical trial to investigate the use of rhenium (<sup>186</sup>Re) obisbameda in two pediatric brain cancers, high-grade glioma and ependymoma, in the of fourth quarter of 2024.

Pediatric high-grade gliomas can be found almost anywhere within the CNS; however, they are most commonly found within the supratentorium. The highest incidence of supratentorial, high-grade gliomas in pediatrics appears to occur in children aged 15 to 19 years, with a median age of approximately nine years. Overall, pediatric high-grade glioma confers a three-year progression free survival (“PFS”) of 11 ± 3% and three-year OS of 22% ± 5%. One-year PFS is as low as 40% in recent trials. Ependymomas are slow-growing central nervous system tumors that involve the ventricular system. Diagnosis is based on MRI and biopsy and survival rate depends on tumor grade and how much of the tumor can be removed. Grade II pathology was associated with significantly improved OS compared to Grade III (anaplastic) pathology (five-year OS = 71 ± 5% vs. 57 ± 10%; p = 0.026). Gross total resection compared to subtotal resection was associated with significantly improved OS (five-year OS = 75 ± 5% vs. 54 ± 8%; p = 0.002).

Overall, pediatric HGG and ependymoma are extremely difficult-to-treat pediatric brain tumors, frequently aggressive, and in recurrent settings, carry an extremely poor prognosis.

Effective September 1, 2024, we entered into an agreement with the Department of Defense (“DoD”) office of the Congressionally Directed Medical Research Programs to receive a \$3.0 million fund for research and development purposes (“DoD Award”) over a three-year period. The DoD Award will be used to support the planned expansion of our clinical trial for pediatric brain cancer. We anticipate beginning enrollment for our Phase 1 ReSPECT-PBC clinical trial in the first quarter of 2025.

#### *Rhenium-188 NanoLiposome Biodegradable Alginate Microsphere Technology*

In January 2022, we announced that we licensed Biodegradable Alginate Microsphere (“BAM”) patents and technology from The University of Texas Health Science Center at San Antonio (“UTHSCSA”) 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 Technetium99m-BAM was intra-arterially delivered to a bovine kidney perfusion model was presented at Society of Interventional Radiology Annual Scientific Meeting. The study concluded that the technology required for radiolabeling BAM could successfully deliver, embolize and retain radiation in the target organ. <sup>188</sup>RNL-BAM

is a preclinical investigational device we intend to further develop and move into clinical trials. Specifically, in 2022 we transferred the <sup>188</sup>RNL-BAM technology from UTHSCSA, and began planning to develop the product and complete early preclinical studies to support a future FDA IND submission. Our intended initial clinical target is liver cancer which is the sixth most common and third deadliest cancer worldwide. It is a rare disease with increasing U.S. annual incidence (42,000) and deaths (30,000).

On July 26, 2023, the FDA responded to a Pre-IND submission that the <sup>188</sup>RNL-BAM product under development would likely be subject to regulation as a medical device under the Federal Food, Drug, and Cosmetic Act (the “FDCA”), rather than as a drug product.

## **Recent Developments**

### *Manufacturing agreement with SpectronRx*

On November 5, 2024, we entered into a manufacturing services agreement for drug product development and manufacturing (the “SpectronRx Services Agreement”) with NukeMed, Inc. d/b/a SpectronRx (“SpectronRx”), pursuant to which SpectronRx will process development and manufacturing clinical investigational pharmaceutical products to support our clinical programs. Based on the SpectronRx Services Agreement, an initial proposal for drug product development and manufacturing under the SpectronRx Services Agreement will become effective January 2025.

Under the SpectronRx Services Agreement, we will own all rights and interest in all intellectual property, including (i) rights related to copyright, patent, trademark, or other right to ideas, inventions, products, programs, procedures, process, formats, and other materials, (ii) developed solely by us in connection with developing, formulating, manufacture, filing, processing, packaging, analyzing or testing of a (a) pharmaceutical ingredient or any intermediate thereof (“API/Drug Substance”), (b) drug product comprised of API/Drug Substance (“Drug Candidate”), or (c) intermediate(s) of (a) or (b) (together with API/Drug Substance and Drug Candidate, the “Product”), or (iii) directly related to the services rendered by SpectronRx or its subcontractors. SpectronRx will own all rights and interest in the intellectual property and owned by or licensed to SpectronRx other than in connection with Products or services covered under the SpectronRx Services Agreement (the “SpectronRx Technology”). To the extent that any portion of SpectronRx Technology is required for the purpose of using or applying the Products, SpectronRx is required to provide to us a non-exclusive, royalty-free, perpetual license for that portion of SpectronRx Technology that is required by us to use and apply the Products.

Under the SpectronRx Services Agreement, upon written notice by us to SpectronRx, at least six months in advance of our first commercial manufacturing needs for a Product, SpectronRx will be required to enter into good faith negotiations with us for a commercial supply agreement governing the manufacturing of such Product for commercial sale or use.

Unless earlier terminated, the SpectronRx Services Agreement will remain in place for a period of five years. Thereafter, the SpectronRx Services Agreement will automatically renew for successive one year terms unless either party notifies the other, not later than six months in advance of the original term or any additional renewed term, of the intention to terminate it. We may terminate the SpectronRx Services Agreement (i) for any reason on prior written notice to SpectronRx, provided that we will be required to compensate SpectronRx for certain fees and costs if such cancellation is made prior to the completion of a work order, or (ii) immediately if SpectronRx files for bankruptcy, becomes insolvent, or is suspended or debarred by the FDA or the United States government. In addition, either party may terminate the SpectronRx Services Agreement within thirty days upon any material breach that is left uncured by the other party.

### *Department of Defense Award*

Effective September 1, 2024, we entered into an agreement with the DoD office of the Congressionally Directed Medical Research Programs (CDMRP) to receive the \$3.0 million DoD Award fund for research and development purposes over a three year period. The DoD Award will be used to support the planned expansion of our clinical trial for pediatric brain cancer. On October 4, 2024, we received the first payment under the DoD Award in the amount of \$0.9 million.

### *Research and Development Agreement with Biolab*

On August 21, 2024, we entered into a Research and Collaboration Agreement with Brainlab AG (“Brainlab”), a leading software-driven med-tech company innovating in surgery and radiation therapy, to optimize the planning and convection-enhanced delivery of the Rhenium (<sup>186</sup>Re) Obisbameda targeted radiotherapeutic in our ReSPECT-GBM clinical trial. We and Brainlab bear our own costs and expenses incurred with the activities under the Research and Collaboration Agreement. As part of the agreement, we will provide pseudonymized data which Brainlab will utilize for data analysis, research and development purposes and Brainlab will provide imaging data analysis services and reports summarizing its finding based on the pseudonymized data in conjunction with our ReSPECT-GBM clinical trial.

### *Recent Financings*

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

## Results of Operations

### Grant Revenue

We recognized \$1.5 million and \$1.3 million, and \$4.4 million and \$3.6 million of grant revenue during the three and nine months ended September 30, 2024 and 2023, respectively, which represents CPRIT's share of the costs incurred for our rhenium (<sup>186</sup>Re) obisbameda development for the treatment of patients with LM.

### Research and development expenses

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

The following table summarizes the components of our research and development expenses for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 2,844	\$ 2,477	\$ 8,343	\$ 6,846
Stock-based compensation	14	16	51	50
Total research and development expenses	<u>\$ 2,858</u>	<u>\$ 2,493</u>	<u>\$ 8,394</u>	<u>\$ 6,896</u>

Research and development expenses increased by approximately \$0.4 million during the three months ended September 30, 2024 as compared to the same period in 2023. The increase was due primarily to an increase of \$0.2 million in compensation expenses, an increase of approximately \$0.6 million of professional research and development service fees, and an increase of \$0.2 million in depreciation and other expenses, offset by a reduction of \$0.6 million in clinical expenses.

Research and development expenses increased by approximately \$1.5 million during the nine months ended September 30, 2024 as compared to the same period in 2023. The increase was due primarily to an increase of \$1.1 million increases in professional services, an increase of \$0.5 million in compensation expenses, an increase of \$0.2 million for depreciation and legal expenses, offset by a reduction of \$0.4 million in clinical expenses.

We expect aggregate research and development expenses to increase during the remainder of 2024 as compared to the corresponding comparable period ended December 31, 2023 as we continue to advance and expand our research programs.

### General and administrative expenses

General and administrative expenses include costs for administrative personnel, legal and other professional expenses, and general corporate expenses. The following table summarizes the general and administrative expenses for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
General and administrative	\$ 2,286	\$ 1,866	\$ 6,442	\$ 5,789
Stock-based compensation	111	132	371	378
Total general and administrative expenses	<u>\$ 2,397</u>	<u>\$ 1,998</u>	<u>\$ 6,813</u>	<u>\$ 6,167</u>

General and administrative expenses increased by approximately \$0.4 million during the three months ended September 30, 2024, as compared to the same period in 2023, primarily due to an increase of legal and professional expenses of \$0.3 million and an increase of \$0.1 million in compensation expenses.

General and administrative expenses increased by approximately \$0.6 million during the nine months ended September 30, 2024, as compared to the same period in 2023, primarily due to an increase of legal and professional expenses of \$0.6 million and an increase of \$0.1 million in compensation expenses, offset by a reduction of \$0.1 million in insurance and travel expenses.

We expect general and administrative expenditures to remain generally consistent during the remainder of 2024 as compared with the corresponding comparable period ended December 31, 2023.

### Stock-based compensation expense

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

The following table summarizes the components of our stock-based compensation expenses for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 14	\$ 16	\$ 51	\$ 50
General and administrative	111	132	371	378
Total stock-based compensation	<u>\$ 125</u>	<u>\$ 148</u>	<u>\$ 422</u>	<u>\$ 428</u>

Our share-based compensation expenses, which are impacted by grants of share-based options, vesting schedule of such grants, as well as grant-date fair value of share-based awards, remained consistent for the three and nine months ended September 30, 2024 and 2023.

### Financing items

The following table summarizes other income (expense) for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Financing expense	\$ —	\$ —	\$ (3,545)	\$ —
Change in fair value of warrants	960	—	5,654	—
Warrant issuance costs	(54)	—	(486)	—
Interest income	80	119	219	290
Interest expense	(61)	(87)	(122)	(333)
Total	<u>\$ 925</u>	<u>\$ 32</u>	<u>\$ 1,720</u>	<u>\$ (43)</u>

The decrease in interest expense for the three and nine months ended September 30, 2024 as compared to the same periods in 2023 was primarily due to the repayment of debt principal of \$1.6 million during the year ended December 31, 2023 and \$4.0 million during the nine months ended September 30, 2024, offset by interest expenses on our line of credit facility. Interest income decreased for the three and nine months ended September 30, 2024 compared with the same periods in 2023 primarily due to a lower average cash and investment balances in year to date 2024 offset by a higher interest rate environment and accreted income on our available-for-sale securities.

We recognized approximately \$3.5 million in financing expense in the condensed consolidated statement of operations during the three and nine months ended September 30, 2024, which represents the excess of the fair value of the Series A Warrants and Series B Warrants at issuance over the proceeds. During the three and nine months ended September 30, 2024, we recognized a net fair value gain on warrant liability of \$1.0 million and \$5.7 million, respectively. The Series A and Series B Warrants were amended during the three months ended September 30, 2024, resulting the warrants being reclassified from liability to equity of the balance sheet, and no longer required to be recorded at fair value at each period end with change in the fair value recorded in the statement of operations.

In addition, total offering expenses related to the May 2024 Private Placement of \$0.4 million were recorded as a component of other expenses as the entire proceeds were allocated to the warrant liability, which could have been settled with either the Company's common stock or Pre-Funded Warrants, that are exercisable into shares of common stock at any time at the holders' option, but not in cash payment to the holders.

We expect interest expense in 2024 to increase as compared with 2023 due to an expected higher principal balance subject to interest.

## Liquidity and Capital Resources

### Short-term and long-term liquidity

The following is a summary of our key liquidity measures at September 30, 2024 and December 31, 2023 (in thousands):

	September 30, 2024	December 31, 2023
Cash and cash equivalents	\$ 1,223	\$ 8,554
Current assets	\$ 5,364	\$ 9,834
Current liabilities	12,112	10,727
Working capital	\$ (6,748)	\$ (893)

We incurred net losses of \$9.1 million for the nine months ended September 30, 2024. We have an accumulated deficit of \$489.6 million as of September 30, 2024. Additionally, we used net cash of \$9.3 million to fund our operating activities for the nine months ended September 30, 2024. These factors raise substantial doubt about our ability to continue as a going concern.

#### *May 2024 Private Placement*

In May 2024, we entered into a securities purchase agreement, which was subsequently amended, with certain investors, including certain of the Company's directors and executive officers (the "Purchasers"), whereby we issued and sold in a private placement (the "May 2024 Private Placement"): (i) 3,591,532 shares of common stock ("Private Placement Share"), or, at the election of each Purchaser, pre-funded warrants (the "Pre-Funded Warrants") exercisable immediately to purchase shares of common stock. Each Private Placement Share or Pre-Funded Warrant are accompanied by (i) a Series A common warrant ("Series A Warrants") to purchase one share of common stock, for an aggregate of 3,591,532 Series A Warrants, and (ii) one Series B common warrant ("Series B Warrants", and together with the Pre-Funded Warrants and Series A Warrants, the "Warrants") to purchase one share of common stock, for an aggregate of 3,591,532 Series B Warrants. At the closing of the May 2024 Private Placement, we received aggregate up-front gross proceeds of approximately \$7.3 million, before deducting fees and other expenses associated with the closing of the May 2024 Private Placement. If the Warrants are exercised in full we will receive additional gross proceeds of approximately \$12.0 million. None of the Series A and Series B Warrants issued in connection with the May 2024 Private Placement have been exercised as of the filing of this quarterly report on Form 10-Q. See Note 12, Stockholders' Deficit - May 2024 Private Placement, of our unaudited condensed consolidated financial statements for further details.

#### *CPRIT Grant*

On September 19, 2022, we entered into the CPRIT Contract, pursuant to which CPRIT will provide us with the CPRIT Grant of \$17.6 million subject to the terms of the CPRIT Contract, to fund approximately two-thirds of the continued development of rhenium (<sup>186</sup>Re) obisbameda for the treatment of patients with LM. We received \$10.4 million of the available funding under the CPRIT Grant during 2022, 2023 and the nine months ended September 30, 2024, of which we recognized \$4.4 million, \$4.9 million and \$0.2 million of grant revenue during the nine months ended September 30, 2024, and the years ended December 31, 2023 and 2022, respectively. The amounts recognized represents CPRIT's share of the costs incurred for our rhenium (<sup>186</sup>Re) obisbameda development for the treatment of patients with LM. As of September 30, 2024, we had \$0.8 million of deferred revenue related to the CPRIT Grant.

#### *DoD Award*

Effective September 1, 2024, we entered into an agreement with the DoD office of the Congressionally Directed Medical Research Programs (CDMRP) to receive a \$3.0 million fund for research and development purposes over a three year period. The DoD Award will be used to support the planned expansion of our clinical trial for pediatric brain cancer. On October 4, 2024, we received the first payment under the DoD Award in the amount of \$0.9 million.

#### *Private Equity Lines*

On August 2, 2022, we entered into a purchase agreement (the "2022 Purchase Agreement") and registration rights agreement pursuant to which Lincoln Park Capital Fund ("Lincoln Park") committed to purchase up to \$50.0 million of shares of our common stock. Under the terms and subject to the conditions of the 2022 Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to \$50.0 million of shares of our common stock, provided that we cannot sell more than 57.5 million shares pursuant to the 2022 Purchase Agreement. Sales of common stock by us are subject to certain limitations, and can occur from time to time, at our sole discretion, over the 36-month period commencing on August 17, 2022, subject to the satisfaction of certain conditions. Actual sales of shares of common stock to Lincoln Park under the 2022 Purchase Agreement depend on a variety of factors to be determined by us from time to time, including, among others, market conditions, the trading price of the common stock and our determinations as to the appropriate sources of funding for the Company and its operations. As consideration for Lincoln Park's irrevocable commitment to purchase shares of our common stock upon the terms of and subject to satisfaction of the conditions set forth in the 2022 Purchase Agreement, we paid \$0.1 million in cash as an Initial Commitment Fee and issued 32,846 as the initial commitment

shares to Lincoln Park in consideration for its commitment to purchase shares of our common stock at our direction under the 2022 Purchase Agreement.

On August 17, 2022, a registration statement (the “First Registration Statement”) was declared effective covering the resale of up to 633,333 shares of our common stock comprised of (i) the 32,846 initial commitment shares, and (ii) up to 600,486 shares that we have reserved for issuance and sale to Lincoln Park under the 2022 Purchase Agreement. We issued and sold 527,166 shares of common stock to Lincoln Park in connection with the First Registration Statement. An additional commitment fee equal to 2.5% of the remainder of the \$50 million will be paid if and when we sell over \$25.0 million of our common stock under the 2022 Purchase Agreement. The additional commitment fee may be paid in cash, common stock, or a combination thereof. We sold approximately 527,166 shares under the First Registration Statement.

On August 18, 2023, a second registration statement (the “Second Registration Statement”) was declared effective covering the resale of up to an additional 1,500,000 shares of our common stock that we reserved for issuance and sale to Lincoln Park under the 2022 Purchase Agreement from time to time. We issued and sold 150,000 shares of common stock to Lincoln Park in connection with the Second Registration Statement. We cannot sell more shares than registered under the Second Registration Statement under the 2022 Purchase Agreement without registering additional shares.

During the period from August 17, 2022 to December 31, 2022, we issued 266,666 shares under the 2022 Purchase Agreement for net proceeds of approximately \$3.2 million. We issued 410,500 shares under the 2022 Purchase Agreement for net proceeds of approximately \$1.0 million from January 1, 2023 to December 31, 2023. No shares of common stock were purchased under the 2022 Purchase Agreement during the nine months ended September 30, 2024.

On January 14, 2022, we entered into an Equity Distribution Agreement (the “January 2022 Distribution Agreement”) with Canaccord, pursuant to which we could issue and sell, from time to time, shares of our common stock in “at-the-market” offerings, having an aggregate offering price of up to \$5 million, depending on market demand, with Canaccord acting as an agent for sales. During the year ended December 31, 2023, we issued 460,151 shares under the January 2022 Distribution Agreement for net proceeds of approximately \$4.8 million. The January 2022 Distribution Agreement was terminated after all available registered shares were fully utilized.

#### *Nasdaq Listing Compliance*

On March 8, 2024, we received a written notice from the Listing Qualifications staff of The Nasdaq Stock Market LLC (“Nasdaq”), notifying us that we no longer complied with the requirement under Nasdaq Listing Rule 5550(b)(1) to maintain a minimum of \$2.5 million in stockholders’ equity (the “Minimum Stockholders’ Equity Requirement”) for continued listing on The Nasdaq Capital Market or the alternative requirements of having a market value of listed securities of \$35 million or net income from continuing operations of \$500,000 in the most recently completed fiscal year or two of the last three most recently completed fiscal years (the “Alternative Standards”).

On September 5, 2024, Nasdaq notified us that we had not regained compliance with Nasdaq Listing Rule 5550(b)(1) and that, as a result, unless we timely requested an appeal of this determination to a Nasdaq Hearings Panel (the “Panel”), Nasdaq would move to suspend trading of our common stock and to have our shares of common stock delisted from The Nasdaq Capital Market. We timely requested a hearing before the Panel, and the hearing was held on October 22, 2024.

On October 30, 2024, we received a decision from the Panel, notifying us that we had until March 4, 2025, to demonstrate compliance with the Minimum Stockholders’ Equity Requirement. The Panel also required that we file a public disclosure on or before March 4, 2025 and describe the transactions undertaken by us to achieve compliance and demonstrate long-term compliance with the Minimum Stockholders’ Equity Requirement. The Panel also noted that it is a requirement during the exception period that we provide prompt notification to the Panel of any significant events that occur during this time that may affect our compliance with Nasdaq’s requirements. This includes, but is not limited to, any event that may call into question our ability to meet the terms of the exception granted. The Panel reserved the right to reconsider the terms of its decision based on any event, condition or circumstance that exists or develops that would, in the opinion of the Panel, make continued listing of our securities on The Nasdaq Capital Market inadvisable or unwarranted.

#### *Funding and Material Cash Requirements*

To date, our operating losses have been funded primarily from outside sources of invested capital from issuance of shares of our common and preferred stocks, proceeds from the now-repaid in full term loan with Oxford Finance, LLC (“Oxford”), the Pershing Credit Facility and grant funding. However, the Company has had, and will continue to have, an ongoing need to raise additional cash from outside sources through a combination of equity offerings, debt financings and potential collaboration, license or development agreements to fund our future clinical development programs and other operations in the next twelve months from the filing of this quarterly report on Form 10-Q. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or

restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. There can be no assurance that we will be able to continue to raise additional capital in the future. Our inability to raise additional cash would have a material adverse impact on our operations, implementation of our strategy and ability to maintain compliance with applicable requirements, including Nasdaq listing rules.

Our present and future funding and cash requirements will depend on many factors, including, among other things:

- the progress, timing and completion of our ongoing and planned clinical trials and nonclinical studies;
- our ability to receive, and the timing of receipt of, future regulatory approvals for our product candidates and the costs related thereto;
- the development and utility of the CNSide Test;
- the scope, progress, results and costs of our ongoing and planned operations;
- the costs associated with expanding our operations and building our sales and marketing capabilities;
- our ability to establish strategic collaborations;
- the cost and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the revenue, if any, received from commercial sales of our product candidates, if approved; and
- potential new product candidates that the Company identifies and attempt to develop.

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

Cash (used in) provided by operating, investing, and financing activities for the nine months ended September 30, 2024 and 2023 is summarized as follows (in thousands):

	<b>Nine Months Ended September 30,</b>	
	<b>2024</b>	<b>2023</b>
Net cash used in operating activities	\$ (9,343)	\$ (10,970)
Net cash used in investing activities	(4,175)	(118)
Net cash provided by financing activities	6,187	3,974
Net decrease in cash and cash equivalents	<u>\$ (7,331)</u>	<u>\$ (7,114)</u>

#### *Material Cash Obligations*

Under the CPRIT Contract we receive matching funds for approximately two-thirds of the development costs for the development of rhenium (<sup>186</sup>Re) obisbameda for the treatment of patients with LM, subject to various funding conditions. The CPRIT Contract is effective for three years, unless otherwise terminated pursuant to the terms of the contract. CPRIT may require us to repay some or all of the disbursed CPRIT grant proceeds (with interest not to exceed 5% annually) in the event of the early termination of the CPRIT Contract.

Under our Pershing Credit Facility, we have ongoing principal and interest payment obligations (see Note 6, Line of Credit Facility, of the condensed consolidated financial statements for further details). In addition, 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.

Other than as described above, we have no purchase commitments or long-term contractual obligations, except for lease obligations as of September 30, 2024. In addition, we have no off-balance sheet arrangements (as defined in the rules and regulations of the SEC) that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

### *Operating activities*

Net cash used in operating activities for the nine months ended September 30, 2024 was \$9.3 million compared to \$11.0 million in the same period of 2023. Our operational cash use decreased \$1.6 million during the nine months ended September 30, 2024 as compared to the same period in 2023, due primarily to increased reimbursement under the CPRIT grant agreement for research and development costs related to the ReSPECT-LM program.

### *Investing activities*

Net cash used in investing activities for the nine months ended September 30, 2024 was related to purchase of Biocept assets of \$0.5 million, purchase of short-term investments of \$7.1 million, redemption of short-term investments of \$3.7 million, and purchases of fixed assets of \$0.1 million. Net cash used in investing activities for the nine months ended September 30, 2023 was related to purchases of fixed assets of \$0.1 million.

### *Financing Activities*

Net cash provided by financing activities for the nine months ended September 30, 2024 was related to net proceeds of \$7.3 million raised by the May 2024 Private Placement, and drawdown of \$3.3 million from the Pershing Credit Facility, offset by repurchase of treasury stock for approximately \$0.4 million and repayment of principle balance under the Oxford loan of \$4.0 million.

Net cash provided by financing activities for the nine months ended September 30, 2023 was primarily related to the net proceeds from sales of shares of common stock of \$5.2 million through the September 2022 Distribution Agreement with Canaccord and the 2022 Purchase Agreement, offset by \$1.2 million of principal repayment under our Term Loan.

### **Critical Accounting Policies and Significant Estimates**

The preparation of consolidated 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 consolidated 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 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, 2023 and there have been no material changes during the nine months ended September 30, 2024 except as described below.

#### *Warrant Liability*

Accounting for liability classified warrants requires management to exercise judgment and make estimates and assumptions regarding their fair value (for more information about the material inputs and assumptions used to value the liability classified warrants refer to Note 4, Fair Value Measurements, of our condensed consolidated financial statements). The warrant liabilities are initially recorded at fair value upon the date of issuance and subsequently remeasured to fair value at each reporting date, with changes recognized in the condensed consolidated statements of operations. Changes in the fair value of the liability classified warrants will continue to be recognized until the warrants are exercised, expire or qualify for equity classification.

In May 2024, the Company issued the Series A Warrants and Series B Warrants and classified them as liabilities because in certain circumstances they could have been exercised into either shares of common stock or Pre-Funded Warrants at the holder's option and thus failed the indexation guidance under ASC 815, Derivatives and Hedging. On August 9, 2024, the Company amended and restated the Series A Warrants and Series B Warrants (the "Amendment and Restatements") to eliminate the ability of the holder to elect to receive Pre-Funded Warrants in this situation.

As a result of the Amendment and Restatements, the Series A Warrants and Series B Warrants, as amended, no longer fail the indexation guidance under ASC 815, Derivatives and Hedging, and the balance of the warrant liability at the amendment date, in the amount of \$5.2 million, was reclassified to equity. As a result, as of the amendment date, there was a corresponding increase in our condensed statements of stockholders' equity.

### **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 of 1934, as amended (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 SEC’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 on Form 10-Q.

#### *Changes in Internal Control over Financial Reporting*

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2024, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **Item 1. Legal Proceedings**

None.

### **Item 1A. Risk Factors**

***We have been notified by Nasdaq of our failure to comply with the minimum stockholders’ equity continued listing requirement and, if we are unable to regain compliance with it or other applicable continued listing requirements and standards of Nasdaq, our common stock could be delisted from Nasdaq.***

Shares of our common stocks are currently listed on The Nasdaq Capital Market. In order to maintain that listing, we must satisfy continued listing requirements and standards. There can be no assurances that we will be able to comply with the applicable listing standards of Nasdaq.

As previously disclosed, on March 8, 2024, we received the Notice from the Listing Qualifications staff of Nasdaq, notifying us that we no longer complied with the requirement under Nasdaq Listing Rule 5550(b)(1) to maintain the Minimum Stockholders’ Equity Requirement for continued listing on The Nasdaq Capital Market or the Alternative Standards.

On September 5, 2024, Nasdaq notified us that we had not regained compliance with Nasdaq Listing Rule 5550(b)(1) and that, as a result, unless we timely requested an appeal of this determination to a Nasdaq Hearings Panel (the “Panel”), Nasdaq would move to suspend trading of our common stock and to have our shares of common stock delisted from The Nasdaq Capital Market. We timely requested a hearing before the Panel, and the hearing was held on October 22, 2024.

On October 30, 2024, we received a decision from the Panel, notifying us that we had until March 4, 2025, to demonstrate compliance with the Minimum Stockholders’ Equity Requirement. The Panel also required that us to file a public disclosure on or before March 4, 2025 and describe the transactions undertaken by us to achieve compliance and demonstrate long-term compliance with the Minimum

Stockholders' Equity Requirement. The Panel also noted that it is a requirement during the exception period that we provide prompt notification to the Panel of any significant events that occur during this time that may affect our compliance with Nasdaq's requirements. This includes, but is not limited to, any event that may call into question our ability to meet the terms of the exception granted. The Panel reserved the right to reconsider the terms of its decision based on any event, condition or circumstance that exists or develops that would, in the opinion of the Panel, make continued listing of the Company's securities on The Nasdaq Capital Market inadvisable or unwarranted.

In the event that our common stock is delisted from Nasdaq, as a result of our failure to comply with the Minimum Stockholders' Equity Requirement, or as a result of our failure to continue to comply with any other requirement for continued listing 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 common 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 decline.

***We may issue additional shares of common stock or other equity securities without our stockholder approval, and holders of warrants and other securities convertible into shares of our common stock may choose to exercise their warrants and other securities requiring us to issue shares of common stock; all of these actions would dilute your ownership interest and may depress the market price of our common stock.***

In May 2024, we entered into a securities purchase agreement with certain investors, including certain of our directors and executive officers, and issued and sold in a private placement: (i) an aggregate of 3,591,532 shares of common stock (or in lieu of shares of common stock, Pre-Funded Warrants), and (ii) Warrants to purchase up to 7,183,064 shares of common stock. If these Warrants are exercised, it will result in significant dilution to our stockholders. See Note 12 (Stockholders' Deficit - May 2024 Private Placement) for further details regarding the May 2024 Private Placement and the terms of the Warrants.

In addition to the Warrants, we will seek additional sources of financing to continue the clinical development of our product candidates. Outstanding securities convertible into our shares of common stock may also be exercised and restricted stock units may vest resulting in the issuance of additional shares of common stock, which will result in further dilution to our stockholders.

Significant additional capital will be needed in the future to continue our planned operations, including further development of our product candidates, preparing IND or equivalent filings, conducting preclinical studies and clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our shares of common stock.

We may also issue additional shares of common stock or other equity securities of equal or senior rank in the future in connection with, among other things, future acquisitions or repayment of outstanding indebtedness, without stockholder approval, in a number of circumstances. The issuance of additional shares or other equity securities of equal or senior rank would have the following effects:

- existing stockholders' proportionate ownership interest in us will decrease;
- the relative voting strength of each previously outstanding common stock may be diminished; and
- the market price of the common stock may decline.

***We recently acquired the CNSide<sup>®</sup> diagnostic portfolio, and we may not be successful in our efforts to develop, fully utilize and monetize it.***

In April 2024, we completed the acquisition of substantially all of the right, title and interest in CNSide<sup>®</sup>, including the CNSide Test, which is designed to detect, quantify, and monitor tumor status in LM. We are currently evaluating and developing our business plan for developing the CNSide<sup>®</sup> diagnostic portfolio alongside our lead radio therapeutic candidate, rhenium (<sup>186</sup>Re) obisbameda, and seeking partnering opportunities for CNSide<sup>®</sup> but there can be no assurances that we will be able to develop the technology to allow for commercial applications, or successfully utilize and fully integrate CNSide<sup>®</sup> into our operations. We may not generate revenues from or realize the anticipated benefits of CNSide<sup>®</sup> within our expected timeline or at all.

<sup>188</sup> ***RNL-BAM will be regulated as a medical device, which may result in additional regulatory and other risks.***

<sup>188</sup>RNL-BAM was developed and tested preclinically as a drug product. The FDA has informed us that <sup>188</sup>RNL-BAM will, moving forward, be regulated instead as a medical device.

In the United States, before we can market a new medical device, we must first receive either clearance under Section 510(k) of the FDCA, or approval of premarket approval (“PMA”), from the FDA, unless an exemption applies. In the process of obtaining premarket clearance or approval following either of these routes, the FDA must determine that a proposed device is either substantially equivalent to a legally marketed predicate device with similar intended uses and the same technological characteristics and risks, or that it is safe and effective for its intended use, based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life sustaining, life supporting or implantable devices.

Modifications to products that are approved through a PMA generally require FDA approval of the modifications through a supplemental application. Both the PMA approval and the 510(k) clearance process can be expensive, lengthy and uncertain. The process of obtaining a PMA is costly and uncertain and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA. In addition, a PMA generally requires the performance of one or more clinical studies. Despite the time, effort and cost, a medical device may not be approved by the FDA. Any delay or failure to obtain necessary regulatory approvals could harm our business. Furthermore, even if we are granted regulatory approvals, they may include significant limitations on the approved and labeled indications for use for the device, which may limit the market for the device.

In addition, comparable foreign regulatory authorities to the FDA have approval policies and regulations related to the safety and performance requirements that apply to <sup>188</sup>RNL-BAM, either as medical devices or as drugs, depending on each jurisdiction’s regulatory requirements. Accordingly, to the extent that we intend to sell medical devices in member states of the European Union or other foreign jurisdictions, the regulatory approval pathway for our product candidates, including <sup>188</sup>RNL-BAM, may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

Failure to successfully develop or supply the <sup>188</sup>RNL-BAM medical device component, delays in or failure of the studies conducted by us, our collaborators, or third-party providers, or failure of our management, our collaborators, or third-party providers to obtain or maintain regulatory approval or clearance of <sup>188</sup>RNL-BAM as a medical device or drug, as applicable in each jurisdiction, could result in increased development costs, delays in or failure to obtain regulatory approval, and associated delays in <sup>188</sup>RNL-BAM reaching the market. Further, failure to successfully develop or supply the device, or to gain or maintain its approval, could adversely affect our operations.

Other than the risk factors set forth above, there have been no material changes to the risk factors disclosed in Part I, Item 1A, “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2023.

#### **Item 5. Other Information**

During the three months ended September 30, 2024, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

**EXHIBIT INDEX  
PLUS THERAPEUTICS, INC.**

Exhibit Number	Exhibit Title	Filed with this Form 10-Q	Incorporated by Reference		
			Form	File No.	Date Filed
3.1	<a href="#">Composite Certificate of Incorporation of Plus Therapeutics, Inc.</a>		10-K	001-34375 Exhibit 3.1	03/11/2016
3.2	<a href="#">Certificate of Amendment to Amended and Restated Certificate of Plus Therapeutics, Inc.</a>		8-K	001-34375 Exhibit 3.1	05/10/2016
3.3	<a href="#">Certificate of Amendment to Amended and Restated Certificate of Plus Therapeutics, Inc.</a>		8-K	001-34375 Exhibit 3.1	05/23/2018
3.4	<a href="#">Certificate of Amendment to Amended and Restated Certificate of Plus Therapeutics, Inc.</a>		8-K	001-34375 Exhibit 3.1	07/29/2019
3.5	<a href="#">Certificate of Amendment to Amended and Restated Certificate of Plus Therapeutics, Inc.</a>		8-K	001-34375 Exhibit 3.1	08/06/2019
3.6	<a href="#">Certificate of Amendment to Amended and Restated Certificate of Plus Therapeutics, Inc.</a>		8-K	001-34375 Exhibit 3.1	04/28/2023
3.7	<a href="#">Amended and Restated Bylaws of Plus Therapeutics, Inc.</a>		8-K	001-34375 Exhibit 3.1	09/21/2021
3.8	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock</a>		8-K	001-34375 Exhibit 3.1	11/28/2017
3.9	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock</a>		8-K	001-34375 Exhibit 3.1	07/25/2018
3.10	<a href="#">Certification of Elimination of the Series F Preferred Stock of Plus Therapeutics, Inc.</a>	X			
4.1	<a href="#">Form of Underwriters' Warrant Amendment Agreement</a>		8-K	001-34375 Exhibit 4.1	10/05/2020
4.2	<a href="#">Form of Pre-Funded Warrant</a>		8-K	001-34375 Exhibit 4.1	05/09/2024
4.3	<a href="#">Form of Series A Warrant (May 2024, as amended and restated August 2024)</a>		10-Q	001-34375 Exhibit 4.5	08/14/2024
4.4	<a href="#">Form of Series B Warrant (May 2024, as amended and restated August 2024)</a>		10-Q	001-34375 Exhibit 4.6	08/14/2024
4.5	<a href="#">Form of Amendment and Restatement of the Plus Therapeutics, Inc. Series A Common Stock Purchase Warrant</a>		10-Q	001-34375 Exhibit 4.7	08/14/2024
4.6	<a href="#">Form of Amendment and Restatement of the Plus Therapeutics, Inc. Series B Common Stock Purchase Warrant</a>		10-Q	001-34375 Exhibit 4.8	08/14/2024
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="#"><u>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</u></a>	X
32.1*	<a href="#"><u>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</u></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 Taxonomy Extension Schema With Embedded Linkbase Documents	X
EX-101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X
EX-101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X
EX-101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X
EX-101.PRE	Inline XBRL Taxonomy Extension 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: November 14, 2024

By: /s/ Marc H. Hedrick

Marc H. Hedrick

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

Dated: November 14, 2024

By: /s/ Andrew Sims

Andrew Sims

*Chief Financial Officer (Duly Authorized Officer and Principal Financial Officer and Principal Accounting Officer)*

