### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549** 

### FORM 8-K

#### **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 20, 2023

### PLUS THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

**Delaware** (State or Other Jurisdiction of Incorporation) 001-34375 (Commission File Number) 33-0827593 (IRS Employer Identification No.)

4200 Marathon Blvd.
Suite 200
Austin, Texas
(Address of Principal Executive Offices)

78756 (Zip Code)

Registrant's Telephone Number, Including Area Code: (737) 255-7194

	(Former	Name or Former Address, if Change	ed Since Last Report)			
	eck the appropriate box below if the Form 8-K filing is iowing provisions:	ntended to simultaneously sa	atisfy the filing obligation of the registrant under any of the			
	Written communications pursuant to Rule 425 under t	he Securities Act (17 CFR 2	30.425)			
	Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)					
	Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))					
	Pre-commencement communications pursuant to Rule	e 13e-4(c) under the Exchang	ge Act (17 CFR 240.13e-4(c))			
	Securities	registered pursuant to Secti	ion 12(b) of the Act:			
		Trading				
	Title of each class	Symbol(s)	Name of each exchange on which registered			
	Common Stock, par value \$0.001 per share	PSTV	The Nasdaq Capital Market			
	icate by check mark whether the registrant is an emergingter) or Rule 12b-2 of the Securities Exchange Act of 1		ed in Rule 405 of the Securities Act of 1933 (§ 230.405 of this oter).			
Em	erging growth company $\square$					
	n emerging growth company, indicate by check mark if evised financial accounting standards provided pursuan	<u> </u>	t to use the extended transition period for complying with any new hange Act. $\square$			

#### Item 2.02 Results of Operations and Financial Condition.

On April 20, 2023, Plus Therapeutics, Inc. (the "Company") reported financial results for the first quarter ended March 31, 2023 and other recent corporate updates. A copy of the press release is furnished as Exhibit 99.1 to this report and incorporated by reference.

The information in this Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1) is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, whether made before or after today's date, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific references in such filing.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.
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Exhibit Number	Description
99.1	Press Release Announcing Financial Results, dated April 20, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

#### **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 hereunto duly authorized.

PLUS THERAPEUTICS, INC.

Date: April 20, 2023 By: /s/ Marc H. Hedrick, M.D.

Marc H. Hedrick, M.D.

President and Chief Executive Officer

#### Plus Therapeutics Reports First Quarter 2023 Financial Results and Business Highlights

Plus completes Phase 1/Part A of the ReSPECT-LM trial Management to host conference call today at 5:00 p.m. ET

AUSTIN, Texas, April 20, 2023 – <u>Plus Therapeutics, Inc.</u>(Nasdaq: <u>PSTV</u>) (the "Company"), a clinical-stage pharmaceutical company developing targeted radiotherapeutics with advanced platform technologies for central nervous system cancers, today announced financial results for the first quarter ended March 31, 2023, and provided an overview of recent business highlights.

"Our team has continued the strong momentum from 2022 through the first quarter of 2023," said Marc H. Hedrick M.D., President and Chief Executive Officer of Plus Therapeutics. "Our 2023 focus is on trial site expansion, patient enrollment and key data readouts for our lead GBM and LM trials, as well as initiating our pediatric trial. Furthermore, we will continue to operate in a capital efficient manner, combining cash on hand with available discretionary sources of capital, existing non-dilutive grant funding and potential new grants we are seeking in 2023."

#### Q1 HIGHLIGHTS AND MILESTONE ACHIEVEMENTS

- Completed Part A of the ReSPECT-LM Phase 1/2a dose escalation clinical trial of rhenium (<sup>186</sup>Re) obisbemeda for the treatment of leptomeningeal metastases (LM).
- Increased enrollment in the ReSPECT-GBM trials including both the Phase 1/2a dose escalation trial and in the Phase 2b trial for small- to medium-sized tumors.
- Enrolled the required three patients in cohort 8 of the Phase 1/2a dose escalation arm at a dose of 41.5 millicuries of radiation in 16.3 milliliters.
- Added Northwestern Memorial Hospital in Chicago, a world-class medical center and leader in clinical research as an enrolling ReSPECT-LM site.

#### FIRST QUARTER 2023 FINANCIAL RESULTS

- The Company's cash balance was \$12.7 million at March 31, 2023, compared to \$18.1 million at December 31, 2022.
- The Company recognized \$506,000 of grant revenue in the first quarter of 2023, which represents the Cancer Prevention & Research Institute of Texas' (CPRIT) share of costs incurred in the development of rhenium (<sup>186</sup>Re) obisbemeda for the treatment of patients with LM.
- Total operating expenses for the first quarter of 2023 were \$5.2 million, compared to total operating expenses of \$3.9 million for the same period the prior year. The increase is due primarily to a \$750,000 license payment to NanoTx Corp for successfully meeting a key clinical milestone and related clinical expenses due to increased enrollment in the Company's lead development programs.
- In addition to current cash on hand, the Company benefits from grant awards of \$3 million from the National Institutes of Health (NIH) and \$17.6 million from CPRIT. The Company also has discretionary, or stockholder approved access to capital from its ATM and equity line of credit of at least \$49 million. In aggregate, these capital sources could provide sufficient capital to fund currently planned and anticipated activities through 2025, if fully utilized.
- Net loss for the first quarter of 2023 was \$4.8 million, or \$(0.14) per share, compared to a net loss of \$4.1 million, or \$(0.19) per share, for the same period the prior year.

#### **UPCOMING EVENTS AND MILESTONES**

During 2023, the Company expects to accomplish the following key business objectives:

- Publish ReSPECT-GBM Phase 1 data in a peer-reviewed journal.
- Present safety and efficacy data from ReSPECT-GBM trials in the second half of 2023.
- Present safety and efficacy data of Phase 1/Part A of the ReSPECT-LM trial in the second half of 2023.
- Initiate the Phase 1/Part B of the ReSPECT-LM trial in the second half of 2023 following a U.S. Food and Drug Administration (FDA) type C meeting.
- Complete key enrollment and site expansion activities in the ReSPECT-GBM Phase 2b trial for full trial enrollment by year-end 2024.
- Initiate the Phase 1 ReSPECT-PBC trial for pediatric patients with ependymoma and high-grade glioma.
- Determine the appropriate FDA regulatory designation for the <sup>186</sup>RNL-BAM technology and complete key development activities.
- Complete key preclinical synergistic drug combination studies of rhenium (<sup>186</sup>Re) obisbemeda and systemic therapies for GBM and LM.
- Submit multiple grant applications to secure non-dilutive capital to support expansion of the Company's drug development pipeline.

#### FIRST QUARTER 2023 RESULTS CONFERENCE CALL

The Company will hold a conference call and live audio webcast at 5:00 p.m. Eastern Time today to discuss its financial results and provide a general business update.

A live webcast will be available at ir.plustherapeutics.com/events.

Participants may also pre-register any time before the call <u>here</u>. Once registration is completed, participants will be provided a dial-in number with a personalized conference code to access the call. Please dial in 15 minutes prior to the start time. Following the live call, a replay will be available on the Company's website under the <u>'For Investor'</u>section. The webcast will be available on the Company's website for 90 days following the live call.

#### **About Plus Therapeutics**

Plus Therapeutics, Inc. is a clinical-stage pharmaceutical company developing targeted radiotherapeutics for difficult-to-treat cancers of the central nervous system with the potential to enhance clinical outcomes for patients. Combining image-guided local beta radiation and targeted drug delivery approaches, the Company is advancing a pipeline of product candidates with lead programs in recurrent glioblastoma (GBM) and leptomeningeal metastases (LM). The Company has built a robust supply chain through strategic partnerships that enable the development, manufacturing and future potential commercialization of its products. Plus Therapeutics is led by an experienced and dedicated leadership team and has operations in key cancer clinical development hubs including Austin and San Antonio, Texas. For more information, visit <a href="https://plustherapeutics.com/">https://plustherapeutics.com/</a>.

#### **Cautionary Statement Regarding Forward-Looking Statements**

This press release contains statements that may be deemed "forward-looking statements" within the meaning of U.S. securities laws. All statements in this press release other than statements of historical fact are forward-looking statements. These forward-looking statements may be identified by future verbs, as well as terms such as "designed to," "will," "can," "potential," "focus," "preparing," "next steps," "possibly," and similar expressions or the negatives thereof. Such statements are based upon certain assumptions and assessments made by

management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate. These statements include, without limitation, statements regarding the following: the potential promise of <sup>186</sup>Re including the ability of <sup>186</sup>Re to safely and effectively deliver radiation directly to the tumor at high doses; expectations as to the Company's future performance including the next steps in developing the Company's current assets; the Company's clinical trials including statements regarding the timing and characteristics of the Respect-GBM and Respect-LM clinical trials; possible negative effects of <sup>186</sup>Re; the continued evaluation of <sup>186</sup>Re including through evaluations in additional patient cohorts; and the intended functions of the Company's platform and expected benefits from such functions.

The forward-looking statements included in this press release are subject to a number of risks and uncertainties that may cause actual results to differ materially from those discussed in such forward-looking statements. These risks and uncertainties include, but are not limited to: the Company's 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 the Company's product candidates and therapies, the results of the Company's research and development activities, including uncertainties relating to the clinical trials of its product candidates and therapies; the Company's liquidity and capital resources and its ability to raise additional cash, the outcome of the Company's partnering/licensing efforts, risks associated with laws or regulatory requirements applicable to it, market conditions, product performance, litigation or potential litigation, and competition within the cancer diagnostics and therapeutics field, among others; and additional risks described under the heading "Risk Factors" in the Company's Securities and Exchange Commission filings, including in the Company's annual and quarterly reports. There may be events in the future that the Company is unable to predict, or over which it has no control, and its business, financial condition, results of operations and prospects may change in the future. The Company assumes no responsibility to update or revise any forward-looking statements to reflect events, trends or circumstances after the date they are made unless the Company has an obligation under U.S. federal securities laws to do so.

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

	March 31, 2023		December 31, 2022	
Assets				
Current assets:				
Cash and cash equivalents	\$	12,723	\$	18,120
Other current assets		906		3,697
Total current assets		13,629		21,817
Property and equipment, net		1,276		1,324
Operating lease right-use-of assets		270		248
Goodwill		372		372
Intangible assets, net		79		94
Other assets		12		12
Total assets	\$	15,638	\$	23,867
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable and accrued expenses	\$	6,495	\$	10,134
Operating lease liability		107		110
Term loan obligation, current		5,057		1,608
Deferred grant liability, current		1,137		_
Total current liabilities		12,796		11,852
Term loan obligation		_		3,786
Noncurrent operating lease liability		166		141
Deferred grant liability		_		1,643
Total liabilities		12,962		17,422
Stockholders' equity:				
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 1,953 and 1,952 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively		_		_
Common stock, \$0.001 par value; 100,000,000 shares authorized; 36,123,833 and 33,601,373 issued and outstanding at March 31, 2023 and December 31, 2022, respectively		36		34
Additional paid-in capital		474,630		473,596
Accumulated deficit		(471,990)		(467,185 <mark>)</mark>
Total stockholders' equity		2,676		6,445
Total liabilities and stockholders' equity	\$	15,638	\$	23,867

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

	Fo	For the Three Months Ended March 31,			
		2023		2022	
Grant revenue	\$	506	\$	-	
Operating expenses:					
Research and development		2,983		1,785	
General and administrative		2,243		2,141	
Total operating expenses		5,226		3,926	
Operating loss		(4,720)		(3,926)	
Other income (expense):					
Interest income		51		7	
Interest expense		(134)		(198)	
Change in fair value of liability instruments				1	
Loss on disposal of property and equipment		(2)		_	
Total other expense	·	(85)		(190)	
Net loss	\$	(4,805)	\$	(4,116)	
Net loss per share, basic and diluted	\$	(0.14)	¢	(0.10)	
ivet ioss per suare, basic and unuted	Ф	(0.14)	Ψ	(0.19)	
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders		34,800,260		21,507,061	

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

(in thousands)	For	For the Three Months		s Ended March 31.	
		2023		2022	
Cash flows used in operating activities:					
Net loss	\$	(4,805)	\$	(4,116)	
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation and amortization		158		147	
Amortization of deferred financing costs and debt discount		66		115	
Change in fair value of liability instruments		_		(1)	
Share-based compensation expense		140		180	
Amortization of operating lease right-of-use assets		29		25	
Loss on disposal of property and equipment		2		_	
Increases (decreases) in cash caused by changes in operating assets and liabilities:					
Other current assets		2,791		459	
Accounts payable and accrued expenses		(3,639)		(650)	
Change in operating lease liabilities		(29)		(35)	
Deferred revenue		(506)		_	
Net cash used in operating activities		(5,793)		(3,876)	
Cash flows used in investing activities:					
Purchases of property and equipment		(97)		(210)	
Purchase of intangible assets				(117)	
In process research and development acquired		_		(250)	
Net cash used in investing activities		(97)		(577)	
Cash flows from financing activities:					
Principal payments of term loan obligation		(402)		(402)	
Proceeds from sale of common stock, net		895		7,694	
Net cash provided by financing activities		493	-	7,292	
Net (decrease) increase in cash and cash equivalents		(5,397)		2,839	
Cash and cash equivalents at beginning of period		18,120		18,400	
Cash and cash equivalents at end of period	\$	12,723	\$	21,239	
Supplemental disclosure of cash flows information:					
Cash paid during period for:				_	
Interest	\$	73	\$	87	
Supplemental schedule of non-cash investing and financing activities:					
Unpaid offering cost	\$	25	\$	171	
Right-of-use assets obtained in exchange for operating lease liability	\$	51	\$	_	

# Investor Contact Peter Vozzo ICR Westwicke (443) 377-4767 Peter.Vozzo@westwicke.com

**Media Contact** 

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