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): November 14, 2024

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)

Title of each class

Common Stock, par value \$0.001 per share

78756 (Zip Code)

Name of each exchange on which registered

The Nasdaq Capital Market

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

(Former Name or Former Address, if Changed Since Last Report) Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions: Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425) 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 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)) Securities registered pursuant to Section 12(b) of the Act:

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this

Trading Symbol(s)

PSTV

chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company \square

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 financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. \Box

Item 2.02 Results of Operations and Financial Condition.

On November 14, 2024, Plus Therapeutics, Inc. (the "Company") reported financial results for the third quarter ended September 30, 2024 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. Exhibit Number	Description
<u>99.1</u>	Press Release Announcing Financial Results, dated November 14, 2024.
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: November 14, 2024 By: /s/ Marc H. Hedrick, M.D.

Marc H. Hedrick, M.D.

President and Chief Executive Officer

Plus Therapeutics Reports Third Quarter 2024 Financial Results and Recent Business Highlights

Obtained agreement from FDA to initiate a Phase 1 trial evaluating multiple doses of Rhenium (186Re) Obisbemeda for the treatment of patients with leptomeningeal metastases (LM)

Presented positive ReSPECT-GBM Trial Data at the 2024 Congress of Neurological Surgeons Annual Conference

Established Radiotherapeutic Manufacturing Partnership with SpectronRx to meet late-stage clinical and commercial forecasts for Rhenium (186Re) Obisbemeda

AUSTIN, Texas, November 14, 2024 (GLOBE NEWSWIRE) – Plus Therapeutics, Inc. (Nasdaq: PSTV) (the "Company"), a clinical-stage pharmaceutical company developing targeted radiotherapeutics with advanced platform technologies for central nervous system (CNS) cancers, today announced financial results for the third quarter ended September 30, 2024, and provided an overview of recent and upcoming business highlights.

Q3 2024 RECENT HIGHLIGHTS AND MILESTONES

- Completed enrollment in the Phase 1 ReSPECT-GBM trial
- Obtained agreement from FDA to begin enrollment in the ReSPECT-LM multi-administration trial for patients with LM (IND 153715). The trial is expected to begin enrollment in early 2025 at seven U.S. trial sites
- Presented positive ReSPECT-GBM Phase 1/2 Trial update data at the 2024 Congress of Neurological Surgeons Annual Conference, showing Rhenium (¹⁸⁶Re) Obisbemeda continues to demonstrate promising feasibility, safety, response, and efficacy signals across 42 treated patients. Additional details can be found here
- Expanded the ReSPECT-GBM Phase 1/2 Trial to new sites and referral regions: North Shore University in New York and Ohio State University in the Upper Midwest
- Entered into a Research and Collaboration Agreement with Brainlab, a leading, innovative software-driven med-tech company to implement optimized case planning software for convection-enhanced delivery or CED of Rhenium (186Re) Obisbemeda for brain cancers
- Received a \$0.9 million grant payment as part of the \$3 million award by the Department of Defense (DoD) Peer Reviewed
 Cancer Research Program Advancing Cancer Care through Clinical Trials Award to support the clinical development of
 Rhenium (186Re) Obisbemeda for pediatric brain cancer
- Established a GMP manufacturing partnership with SpectronRx to meet late-stage clinical and commercial forecasts for Rhenium (¹⁸⁶Re) Obisbemeda. Additional details can be found here
- Obtained CLIA registration for our Houston-based facility supporting the CNSide Cerebrospinal Fluid Tumor Cell Enumeration Assay Platform, with CLIA compliance certification anticipated in early 2025

"Securing agreement from the FDA to initiate a Phase 1 multiple dose administration trial is a key next step in our integrated development plan for Rhenium (186Re) Obisbemeda for patients with LM," said Marc H. Hedrick, M.D., Plus Therapeutics' President and Chief Executive Officer. "We are on track to complete both Phase 1 LM trials and move to later stage trials in 2025."

UPCOMING EXPECTED EVENTS AND MILESTONES

- Presentations planned for the following upcoming medical conferences:
 - o Society for Neuro-Oncology (SNO) Annual Conference (November 21-24, 2024)
 - Rhenium (¹⁸⁶Re) Obisbemeda (rhenium nanoliposome, ¹⁸⁶RNL) for the treatment of leptomeningeal metastases (LM): Summary of the Phase 1 dose escalation study and Phase 2 administered dose selection
 - CSF Tumor Cell (CSF-TC) Detection, Quantification and Biomarker assessment helps in clinical management of breast cancer and Non-Small Cell Lung cancer patients having Leptomeningeal Disease
 - The Oncogenic Flip in Patients with Leptomeningeal Metastatic Disease (LMD): Longitudinal Detection in Cerebrospinal Fluid Tumor Cells (CSF-TCs) Reveals Implications for Differential Treatment of the LMD Tumor
 - o San Antonio Breast Cancer Symposium (December 10-13, 2024)
 - Rhenium (¹⁸⁶Re) Obisbemeda (rhenium nanoliposome, ¹⁸⁶RNL) for the treatment of leptomeningeal metastases (LM): Update on Phase 1 dose escalation
- Complete ReSPECT-LM Phase 1 single dose administration trial and determine the maximum tolerated and recommended Phase 2 doses by year-end
- Initiate ReSPECT-LM Phase 1 multiple dose administration trial in 2025
- Complete ReSPECT-GBM Phase 2 enrollment by 2025
- Obtain IND approval for a Phase 1/2 trial of Rhenium (186Re) Obisbemeda for pediatric ependymoma and high-grade glioma
- Launch the CNSide Cerebrospinal Fluid Tumor Cell Enumeration Assay Platform as a laboratory-developed test (LDT) in 2025

THIRD QUARTER 2024 FINANCIAL RESULTS

- The Company's cash and investments balance was \$4.8 million at September 30, 2024 compared to \$8.6 million at December 31, 2023. In addition, the Company received a \$0.9 million grant payment from the DoD in October 2024, and is on track to receive the next CPRIT grant advance of \$3.9 million within 90 days following this release
- The Company recognized \$4.4 million in grant revenue year to date through September 30, 2024, compared to \$3.6 million for the same period in 2023, which in both periods represents the Cancer Prevention & Research Institute of Texas' (CPRIT) share of the costs incurred for our Rhenium (186Re) Obisbemeda development for the treatment of patients with LM
- Total operating loss year to date through September 30, 2024, was \$10.8 million compared to \$9.5 million for the same period in 2023. The increase is primarily due to increased spend related to the ReSPECT-LM trial
- Net loss year to date through September 30, 2024, was \$9.1 million, or \$(1.46) per basic share, compared to a net loss of \$9.5 million, or \$(3.54) per basic share, for the same period the prior year

THIRD QUARTER 2024 RESULTS CONFERENCE CALL

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

The live audio webcast will be available at <u>ir.plustherapeutics.com/events</u>.

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 Investors'</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 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 https://plustherapeutics.com/.

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, including statements regarding clinical trials, expected operations and upcoming developments. 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 "expect" "potential," "anticipating," "planning" 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 under the heading Upcoming Events and Expected Milestones, and statements regarding the following: CLIA compliance certification of the Company's Houston-based clinical laboratory; the potential promise of rhenium (186Re) obisbemeda; expectations as to the Company's future performance, including the next steps in developing the Company's product candidates; the Company's clinical trials, including statements regarding the timing and characteristics of the ReSPECT-GBM, ReSPECT-LM and ReSPECT-PBC clinical trials; the continued evaluation of rhenium (186Re) obisbemeda including through evaluations in additional patient cohorts;; development and utility of CNSide leptomeningeal metastases diagnostic test.

The forward-looking statements included in this press release could differ materially from those expressed or implied by these forward-looking statements because of risks, uncertainties, and other factors that include, but are 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, including the ability of the Company to come into compliance with The Nasdaq Capital Market listing requirements; market conditions, product performance, litigation or potential litigation, and competition within the cancer diagnostics and therapeutics field; ability to develop and protect proprietary intellectual property or obtain licenses to intellectual property developed by others

on commercially reasonable and competitive terms; challenges associated with radiotherapeutic manufacturing, production and distribution capabilities necessary to support the Company's clinical trials and any commercial level product demand; and material security breach or cybersecurity attack affecting the Company's operations or property. This list of risks, uncertainties, and other factors is not complete. Plus Therapeutics discusses some of these matters more fully, as well as certain risk factors that could affect Plus Therapeutics' business, financial condition, results of operations, and prospects, in its reports filed with the SEC, including Plus Therapeutics' annual report on Form 10-K for the fiscal year ended December 31, 2023, quarterly reports on Form 10-Q, and current reports on Form 8-K. These filings are available for review through the SEC's website at www.sec.gov. Any or all forward-looking statements Plus Therapeutics makes may turn out to be wrong and can be affected by inaccurate assumptions Plus Therapeutics might make or by known or unknown risks, uncertainties, and other factors, including those identified in this press release. Accordingly, you should not place undue reliance on the forward-looking statements made in this press release, which speak only as of its date. 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.

Investor Contact

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

	September 30, 2024		December 31, 2023	
Assets				
Current assets:				
Cash and cash equivalents	\$	1,223	\$	8,554
Investments		3,565		_
Other current assets				1,280
Total current assets		4,788		9,834
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	\$	6,978	\$	11,388
Liabilities and Stockholders' Equity				
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		<u> </u>		3,976
Total current liabilities		12,112		10,727
Noncurrent operating lease liability		40		85
Deferred grant liability		_		1,924
Total liabilities		12,152		12,736
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		(5,174)		(1,348)
Total liabilities and stockholders' deficit	\$	6,978	\$	11,388

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	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		5,255	4,491		15,207	13,063
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)		925	32		1,720	(43)
Net loss	\$	(2,874)	\$ (3,219)	\$	(9,075) \$	(9,506)
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

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

(In thousands)	For the Nine Mo	For the Nine Months Ended September 30,					
	2024	itiis Enge	2023				
Cash flows used in operating activities:							
Net loss	\$ (9,0	75) \$	(9,506				
Adjustments to reconcile net loss to net cash used in operating activities:							
Depreciation and amortization	5	24	477				
Amortization of deferred financing costs and debt discount		20	160				
Share-based compensation expense	4	22	428				
Accretion of discount on short-term investments	((70)	_				
Non-cash financing expense	3,5	45	_				
Change in fair value of warrants	(5,6	54)	_				
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	7	04	3,190				
Accounts payable and accrued expenses	1,3	26	(4,061				
Change in operating lease liabilities	(97)	(87				
Deferred grant liability	(1,0	84)	(1,643				
Net cash used in operating activities	(9,3	43)	(10,970				
Cash flows used in investing activities:							
Purchases of property and equipment	(1	35)	(118				
Redemption of short-term investments	3,6	50	_				
Purchase of short-term investments	(7,1	45)	_				
Purchase of intangible assets	(5	45)	_				
Net cash used in investing activities	(4,1	75)	(118				
Cash flows provided by financing activities:							
Principal payments of term loan obligation	(3,9	96)	(1,206				
Proceeds from credit facility	3,2	.92	_				
Purchase of treasury stock	(3	74)	_				
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	7,2	65	_				
Net cash provided by financing activities	6,1		3,974				
Net decrease in cash and cash equivalents	(7,3		(7,114				
Cash and cash equivalents at beginning of period	8,5		18,120				
Cash and cash equivalents at end of period	\$ 1,2		11,006				