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 20, 2023

PLUS THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-34375**	**33-0827593**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4200 Marathon Blvd., Suite 200, Austin, Texas 78756
(Address of principal executive offices, with zip code)

(737) 255-7194
(Registrant's telephone number, including area code)

N/A
(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 (see General Instructions A.2. below):

☐ 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:

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

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

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

Item 7.01 Regulation FD Disclosure.

On November 20, 2023, Plus Therapeutics, Inc. (the "Company") issued a press release entitled "Plus Therapeutics Reports New ReSPECT-GBM Phase 2 Trial Data at the Society for NeuroOncology Annual Meeting and will Host Key Opinion Leader Webinar."

The information in this Item 7.01, including Exhibit 99.1 to this Current Report on Form 8-K, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

The Company announced positive data from the ongoing ReSPECT-GBM Phase 2 trial evaluating the Company's lead radiotherapeutic, rhenium (^{186}Re) obisbemeda, 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 include:

- 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 (^{186}Re) Obisbemeda continues to demonstrate a favorable safety profile, despite delivering up to 20x the dose of radiation (up to 740 Gy) typically delivered by external beam radiation therapy (EBRT) for rGBM patients (up to 35 Gy)
- Imaging data presented by Andrew Brenner, MD, PhD is consistent with the efficacy signal of Rhenium (^{186}Re) Obisbemeda in rGBM
- Company to Host Virtual KOL Webinar to Discuss Data Today at 10:00 am ET

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated November 20, 2023 (announcing clinical update)
104	The cover pages of this Current Report on Form 8-K, formatted in Inline XBRL

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.

Date: November 20, 2023

PLUS THERAPEUTICS, INC.

By: /s/ Marc H. Hedrick, M.D.
Marc H. Hedrick, M.D.
President and Chief Executive Officer

Exhibit 99.1

Plus Therapeutics Reports New Interim ReSPECT-GBM Phase 2 Trial Data at the Society for NeuroOncology Annual Meeting and will Host Key Opinion Leader Webinar

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 (^{186}Re) Obisbemeda continues to demonstrate a favorable safety profile, despite delivering up to 20x the dose of radiation (up to 740 Gy) typically delivered by external beam radiation therapy (EBRT) for rGBM patients (up to 35 Gy)

Imaging data presented by Andrew Brenner, MD, PhD is consistent with the efficacy signal of Rhenium (^{186}Re) Obisbemeda in rGBM

Company to Host Virtual KOL Webinar to Discuss Data Today at 10:00 am ET

AUSTIN, Texas, November 20, 2023 (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 cancers, today announced positive data from the ongoing ReSPECT-GBM Phase 2 trial evaluating the Company's lead radiotherapeutic, rhenium (^{186}Re) obisbemeda, for the treatment of recurrent glioblastoma (rGBM) at the Society for NeuroOncology (SNO) 28th Annual Meeting held November 15-19, 2023 in Vancouver, Canada. The Company is hosting a virtual key opinion leader (KOL) webinar to discuss the data today at 10:00 am ET. To register for the event, please click here.

"GBM needs better treatment options, and we are highly encouraged by the initial data from the NIH-supported ReSPECT-GBM Phase 2 trial of rhenium (^{186}Re) obisbemeda in rGBM," said Marc H. Hedrick, M.D., M.B.A., President and Chief Executive Officer of Plus Therapeutics. "We believe the data presented at SNO suggests that rhenium (^{186}Re) obisbemeda confers a survival benefit over published standard of care data and our own real world data assessments of propensity matched controls. Our 2024 focus will be onboarding additional clinical sites, completing Phase 2 enrollment, continuing the phase 1 trial to maximum tolerated dose, and planning next steps for the program."

"The interim ReSPECT-GBM Phase 2 data coupled with the novel imaging analyses reported at SNO further strengthens the compelling therapeutic rationale for the use of rhenium (186Re) obisbemeda on malignant gliomas," said Andrew J. Brenner, M.D., Ph.D., Professor of Medicine, Neurology, and Neurosurgery at The University of Texas Health Science Center at San Antonio and principal investigator of the ReSPECT-GBM clinical trial. "The Phase 2 clinical outcomes thus far, show effects consistent with the group of patients in the Phase 1 dose escalation trial that received both a therapeutic dose of radiation of greater than 100 Gy and tumor coverage of greater than 70%."

Key Highlights from the ReSPECT-GBM Phase 2 Trial

ReSPECT-GBM is an ongoing, first-in-human, open-label, Phase 1/2 study investigating dose escalation and other delivery parameters (i.e., number of catheters (1-5), infusion rates, drug volumes, and drug concentrations) to determine the maximum tolerated dose (MTD), maximum feasible dose (MFD), safety, and efficacy of rhenium (^{186}Re) obisbemeda in recurrent adult glioma (IND 116117).

The primary objective of the Phase 2 study is to assess overall survival (OS) following rhenium (^{186}Re) obisbemeda administration. As of November 14, 2023, 15 patients with rGBM have been treated with rhenium (^{186}Re) obisbemeda at a dose of 22.3 mCi delivered directly to the tumor by Convection Enhanced Delivery (CED).

- In 15 treated patients, mOS is 13 months (95% CI 5 months). Currently, 9 out of the 15 treated patients remain alive.
- Median PFS is 11 months (95% CI 6-11 months).
- The average percent of treated tumor across all 15 patients was 87.2% at 120 hours, with 13/15 patients receiving greater than or equal 70% tumor volume coverage by the drug and ≥100 Gy absorbed dose to the tumor.
- Advanced longitudinal imaging analysis supports the observed efficacy signal of rhenium (^{186}Re) obisbemeda.
- Rhenium (^{186}Re) obisbemeda continues to be generally safe and well tolerated, consistent with data accumulated in the Phase 1 trial.

A copy of the presentations will be made available under the Presentations tab of the Investors section of the Company's website following the meeting at https://ir.plustherapeutics.com.

KOL Webinar to Discuss SNO Data

Plus Therapeutics is hosting a virtual KOL event today, November 20, 2023 at 10:00 am ET to discuss the data presented at SNO. The event will feature neuro-oncology expert and principal investigator Andrew Brenner, M.D., Ph.D. (Professor-Research, Departments of Medicine, Neurology, and Neurosurgery, S & B Kolitz/CTRC-Zachry Endowed Chair Neuro-Oncology Research, Mays Cancer Center at UT Health San Antonio) and neurosurgeons Toral Patel, M.D. (UT Southwestern Medical Center, Peter O'Donnell Jr. Brain Institute) and John Floyd, M.D. (UT Health San Antonio, UT Health Medical Arts & Research Center).

To register for the event, please click here. A replay of the event will be available on Investor Relations section of the Plus Therapeutics website after the event.

About Rhenium (^{186}Re) obisbemeda

Rhenium (^{186}Re) obisbemeda is a novel injectable radiotherapy specifically formulated to deliver highly targeted high dose radiation in CNS tumors in a safe, effective and convenient manner to optimize patient outcomes. Rhenium (^{186}Re) obisbemeda has the potential to reduce risks and improve outcomes for CNS cancer patients, versus currently approved therapies, with a more targeted and potent radiation dose. Rhenium-186 is an ideal radioisotope for CNS therapeutic applications due to its short half-life, beta energy for destroying cancerous tissue and gamma energy for live imaging. Rhenium (^{186}Re) obisbemeda is being evaluated for the treatment of recurrent glioblastoma and leptomeningeal metastases in the ReSPECT-GBM and ReSPECT-LM clinical trials. ReSPECT-GBM is supported by an award from the National Cancer Institute (NCI), part of the U.S. National Institutes of Health (NIH), and ReSPECT-LM is funded by a three-year $17.6M grant by the Cancer Prevention & Research Institute of Texas (CPRIT).

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 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. 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 ^{186}Re including the ability of ^{186}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; the anticipated completion of the ReSPECT-GBM Phase 2 enrollment; the continuation of the ReSPECT-GBM phase 1 trial to maximum tolerated dose and the next phase of the program; the continued evaluation of rhenium (^{186}Re) obisbemeda 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.

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