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 18, 2021

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 18, 2021, Plus Therapeutics, Inc. (the "Company"), issued a press release entitled "Plus Therapeutics Announces Positive Interim Data from ReSPECT™-GBM Phase 1 Clinical Trial at the 2021 Society for Neuro-Oncology Annual Meeting."

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.

On November 18, 2021, the Company released positive interim data on its lead investigational drug, Rhenium-186 NanoLiposome ("^{186}RNL"), from the first-in-man Phase 1 ReSPECT™ clinical trial in patients with recurrent glioblastoma ("GBM"). The ReSPECT trial of ^{186}RNL evaluated 22 patients with GBM over a six-year period. Each patient received a single administration of ^{186}RNL via convection enhanced delivery ("CED").

Key findings include the following:

- No delivery failures were observed and an average absorbed dose of 267.5 Gy (range 8.9-740Gy) of radiation was delivered to the tumor.
- No dose limiting toxicities or adverse events (AEs) with the outcome of death, or discontinuations due to AEs have been observed.
- Of 22 total subjects with recurrent GBM treated with ^{186}RNL, seven patients remain alive and mean and median overall survival (OS) is currently 336.6 days and 231.5 days, respectively.
- In the subset of 13 patients receiving greater than 100 Gy absorbed radiation, seven patients remain alive and mean and median OS is currently at 453.8 days and 330 days respectively.
- No patients remain alive in the cohort of 9 patients receiving less than 100 Gy absorbed radiation and mean and median OS is 167.3 days and 156 days respectively.
- In 10 treated patients in cohorts five through seven, 13.4 millicuries or more of radiation was delivered and 80% received greater than 100 Gy average absorbed dose of radiation to the tumor.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated November 18, 2021 (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 18, 2021

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 Announces Positive Interim Data from ReSPECT™-GBM Phase 1 Clinical Trial at the 2021 Society for Neuro-Oncology Annual Meeting

Latest interim analysis shows Rhenium-186 NanoLiposome (^{186}RNL) well-tolerated without dose-limiting toxicities

Mean and median overall survival in patients receiving absorbed dose greater than 100 Gy is 453.8 days and 330 days, respectively, with seven patients remaining alive

AUSTIN, Texas, November 18, 2021 – Plus Therapeutics, Inc. (Nasdaq: PSTV) (the "Company"), a U.S. clinical-stage pharmaceutical company developing innovative, targeted radiotherapeutics for rare and difficult-to-treat cancers, today released positive interim data on its lead investigational drug, Rhenium-186 NanoLiposome (^{186}RNL), from the first-in-man Phase 1 ReSPECT™-GBM clinical trial in patients with recurrent glioblastoma (GBM) at the 2021 Society for Neuro-Oncology Annual Meeting and Education Day being held in Boston, Massachusetts.

According to the data, ^{186}RNL delivered via convection enhanced delivery (CED) is well-tolerated with favorable overall survival in adult patients at higher absorbed radiation doses (greater than 100 Gy). A positive correlation was observed also between overall survival and higher absorbed radiation doses (greater than 100 Gy).

The poster, titled "*Safety and Feasibility of Rhenium-186 NanoLiposome (^{186}RNL) in Recurrent Glioma: the ReSPECT™ Phase 1 Trial*," outlines data from the ReSPECT™-GBM trial, substantially funded by the U.S. National Institutes of Health/National Cancer Institute, which has thus far evaluated 22 adult patients with recurrent GBM across seven cohorts of increasing dose, treated over a six year period.

"In the ReSPECT™ trial thus far, ^{186}RNL has been well-tolerated without dose-limiting toxicities and we believe further clinical investigation of relative efficacy is warranted," 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 open label, dose escalation trial was not designed to show efficacy but the trends observed linking overall survival and key delivery parameters such as therapeutic radiation dose to the tumor are promising."

Key findings include the following:

- No delivery failures were observed and an average absorbed dose of 267.5 Gy (range 8.9-740Gy) of radiation was delivered to the tumor.
- No dose limiting toxicities or adverse events (AEs) with the outcome of death, or discontinuations due to AEs have been observed.
- Of 22 total subjects with recurrent GBM treated with ^{186}RNL, seven patients remain alive and mean and median overall survival (OS) is currently 336.6 days and 231.5 days, respectively.
- In the subset of 13 patients receiving greater than 100 Gy absorbed radiation, seven patients remain alive and mean and median OS is currently at 453.8 days and 330 days respectively.

- No patients remain alive in the cohort of 9 patients receiving less than 100 Gy absorbed radiation and mean and median OS is 167.3 days and 156 days respectively.
- In 10 treated patients in cohorts five through seven, 13.4 millicuries or more of radiation was delivered and 80% received greater than 100 Gy average absorbed dose of radiation to the tumor.

“Our team is pleased with the clinical performance and the potential promise of ^{186}RNL in patients with this devastating disease,” said Marc Hedrick, M.D., President and Chief Executive Officer of Plus Therapeutics. “In particular, the observation that we may be able to reliably and precisely deliver a significant therapeutic dose of radiation greater than 100 Gy and potentially influence survival is a positive development. We look forward to completing key drug scale-up activities and proceed to FDA discussions regarding CMC and next clinical steps in early 2022.”

For a more detailed discussion of the ReSPECT-GBM trial data, please join the Plus Therapeutics hosted webinar on Thursday, November 18, 2021, 4:00 to 5:00 p.m. ET (details below).

A copy of the poster will be available under the Presentations tab of the Investors section of the Company’s website at https://ir.plustherapeutics.com.

Key Opinion Leader Roundtable Webinar Details

A live webinar with accompanying slides will be available in the Events page of the Investor Relations section of the Plus Therapeutics website. Individuals can participate in an interactive Q&A session by submitting pertinent questions via the webcast platform.

Please log in approximately 10 minutes prior to the scheduled start time of 4:00 p.m. ET on November 18, 2021. The archived webcast will be available in the Events section of the Company’s website for 90 days.

A live audio conference will be available by dialing (833) 340-0285 (toll-free) or (236) 712-2475 and entering Conference ID 3170796.

About Rhenium-186 NanoLiposome

Rhenium-186 NanoLiposome (^{186}RNL) is under investigation as a potentially safe, effective and convenient way to deliver a very high dose of radiation, possibly over 20 times greater than traditional external beam radiation therapy. This trial is supported by the U.S. National Institutes of Health/National Cancer Institute at three trial sites in the U.S., including UT Health Science Center San Antonio, UT Southwestern Medical Center Dallas and UT MD Anderson Cancer Center Houston.

The U.S. Food and Drug Administration has granted both Orphan Drug designation and Fast Track designation to ^{186}RNL for the treatment of patients with GBM. Additional details about the ReSPECT™ trial are available at clinicaltrials.gov (NCT01906385).

About Plus Therapeutics, Inc.

Plus Therapeutics, Inc. is a clinical-stage pharmaceutical company focused on the development, manufacture, and commercialization of complex and innovative treatments for patients battling cancer and other life-threatening diseases.

Our proprietary nanotechnology platform is currently centered around the enhanced delivery of a variety of drugs using novel liposomal encapsulation technology. Liposomal encapsulation has been extensively explored and undergone significant technical and commercial advances since it was first developed. Our platform is designed to facilitate new delivery approaches and/or formulations of safe and effective, injectable drugs, potentially enhancing the safety, efficacy and convenience for patients and healthcare providers. More information may be found at PlusTherapeutics.com and ReSPECT-Trials.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}RNL including the ability of ^{186}RNL 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-LM or the ReSPECT-PBC trials; possible negative effects of ^{186}RNL; the continued evaluation of ^{186}RNL including through evaluations via a seventh patient cohort; 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 regenerative medicine 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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