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)**: September 15, 2020**

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 8.01 Other Events.

On September 15, 2020, Plus Therapeutics, Inc. (the "Company") announced that the U.S. Food and Drug Administration has granted the Company Fast Track designation for its lead investigational drug, Rhenium NanoLiposomes (RNL™), for the treatment of patients with recurrent glioblastoma. A copy of the press release is attached as Exhibit 99.1 to this report and is incorporated herein solely for purposes of this Item 8.01 disclosure.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release Announcing Fast Track Designation, dated September 15, 2020.

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: September 15, 2020

PLUS THERAPEUTICS, INC.

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

Exhibit 99.1

Plus Therapeutics Receives Fast Track Designation for Its Novel Glioblastoma Treatment

AUSTIN, Texas, September 15, 2020 (GLOBE NEWSWIRE) -- Plus Therapeutics, Inc. (Nasdaq: PSTV) (the “Company”), today announced that the U.S. Food and Drug Administration (FDA) has granted the Company Fast Track designation for its lead investigational drug, Rhenium NanoLiposomes (RNL™), for the treatment of patients with recurrent glioblastoma. As previously reported, the Company also received orphan drug designation from the FDA for RNL for the treatment of patients with glioblastoma.

Fast Track designation confers several benefits to the drug development program including 1) more frequent meetings with FDA to discuss the drug's development plan, 2) more frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers, 3) eligibility for Accelerated Approval and Priority Review, if relevant criteria are met, and 4) Rolling Review, which means that a drug company can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. NDA review usually does not begin until the drug company has submitted the entire application to the FDA.

“Fast Track designation validates the potential importance of this novel radiotherapeutic for patients with recurrent glioblastoma who currently have no good treatment options,” said Dr. Marc Hedrick, President and Chief Executive Officer of Plus Therapeutics. “With this designation in hand, we intend to move into Cohort 6 of the trial, one key step closer to bringing forth a novel therapy for these patients.”

RNL is being evaluated in the NIH/NCI-supported, multi-center ReSPECT™ Phase 1 dose-finding clinical trial (NCT01906385). As reported last week, the ReSPECT trials’ Data and Safety Monitoring Board (DSMB) approved the Company to proceed to Cohort 6 of the trial, which includes increasing both the drug volume and radiation dose to 8.8 milliliters (mL) and 22.3 millicuries (mCi), respectively.

RNL is designed to safely, effectively, and conveniently deliver a very high dose of radiation, of up to 25 times greater concentration than currently used external beam radiation therapy, directly into the brain tumor for maximum effect.

About Glioblastoma

Glioblastoma (Grade IV astrocytoma) is the most common and most aggressive of the primary malignant brain tumors in adults. According to the most recent Central Brain Tumor Registry of the United States (CBTRUS) Statistical Report, on average there are nearly 12,0000 cases of glioblastoma diagnosed annually in the U.S., with historical 1-year and 5-year median survival rates of 40.8% and 6.8%, respectively.

About Plus Therapeutics, Inc.

Plus Therapeutics, Inc. (Nasdaq: PSTV) is a clinical-stage pharmaceutical company whose radiotherapeutic portfolio is concentrated on nanoliposome-encapsulated radionuclides for several cancer targets. Central to the Company’s drug development is a unique nanotechnology platform designed to reformulate, deliver and commercialize multiple drugs targeting rare cancers and other diseases. The 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 certain statements that may be deemed “forward-looking statements” within the meaning of U.S. securities laws. All statements, other than statements of historical fact, that address activities, events or developments that we intend, expect, project, believe or anticipate and similar expressions or future conditional verbs such as will, should, would, could or may occur in the future are forward-looking statements. 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: the Company’s potential 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; the Company’s potential to develop drug candidates currently in its product pipeline; and the Company’s potential to develop additional drugs outside of its current pipeline. The forward-looking statements included in this press release are subject to a number of additional material risks and uncertainties, including but not limited to: the risk that the Company is not able to successfully develop product candidates that can leverage the U.S. FDA’s accelerated regulatory pathways; and the 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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