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)**: October 21, 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 per share	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 2.02 Results of Operations and Financial Condition.

On October 21, 2021, Plus Therapeutics, Inc. (the "Company") reported financial results for the quarter ended September 30, 2021 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
99.1	Press Release Announcing Financial Results, dated October 21, 2021.
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.

Date: October 21, 2021

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 Reports Third Quarter 2021 Financial Results and Business Highlights

Management to host conference call today at 5:00 p.m. ET

AUSTIN, Texas, October 21, 2021 – Plus Therapeutics, Inc. (Nasdaq: PSTV) (the "Company"), a clinical-stage pharmaceutical company developing innovative, targeted radiotherapeutics for rare and difficult-to-treat cancers, today announced financial results for the third quarter ended September 30, 2021, and provided an overview of recent business highlights.

"In the third quarter, we made meaningful progress executing our strategy to develop novel radiotherapeutics for rare and central nervous system cancers", said Marc H. Hedrick M.D., President and Chief Executive Officer of Plus Therapeutics. "We increased the ReSPECT-GBM™ trial dose by 40%, were accepted to present an update of the ReSPECT-GBM trial data at the 2021 Society for Neuro-Oncology Annual Meeting in November, received clearance from the U.S. Food and Drug Administration for our Investigational New Drug application for leptomeningeal metastases, entered into an additional agreement for the production of our radiopharmaceutical products, and strengthened our leadership team with the appointment of a highly experienced Chief Medical Officer with decades of radiopharmaceutical development experience."

RECENT HIGHLIGHTS

Rhenium-186 NanoLiposome (^{186}RNL), a novel radiotherapy in development for several rare cancer targets

Recurrent Glioblastoma (GBM)

- The ongoing U.S. multi-center ReSPECT-GBM Phase 1 dose-finding clinical trial is designed to safely and effectively deliver high doses of radiation directly to brain tumors. Thus far, 22 patients with recurrent GBM have been treated in the ReSPECT-GBM trial across eight cohorts. A 40% increase in absorbed radiation doses per tumor in Cohort 8 over Cohort 7 have been achieved without dose-limiting toxicities. Patient recruitment continues at UT Health San Antonio, UT Southwestern in Dallas, and MD Anderson in Houston. Learn more at ClinicalTrials.gov.
- The Company will present interim data from its ReSPECT-GBM clinical trial at the 2021 American Society for Radiation Oncology (ASTRO) Annual Meeting scheduled October 24-27, 2021 and at the 2021 Society for Neuro-Oncology (SNO) Annual Meeting and Education Day scheduled November 18-21, 2021.
- The Company will host a roundtable discussion of the ReSPECT-GBM clinical trial on November 18, 2021 at 4:00 p.m. EST, which will be webcast, with Toral Patel, M.D., Associate Professor, Department of Neurosurgery, UT Southwestern Medical Center, and Andrew J. Brenner, M.D., Ph.D., Professor of Medicine, Neurology, and Neurosurgery at The University of Texas.

Leptomeningeal Metastases (LM)

- The Company received clearance of its Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) for ^{186}RNL for the treatment of LM.
- The Company expects to initiate patient accrual in a Phase 1 dose escalation trial of ^{186}RNL (ReSPECT-LM) in the fourth quarter of 2021.
- ReSPECT-LM will be a multi-center, sequential cohort, open-label, single dose, dose escalation Phase 1 study of the safety, tolerability, biodistribution, dosimetry, and anti-tumor activity of ^{186}RNL given intraventricularly via an Ommaya reservoir to subjects over 18 years old with LM. The primary endpoints of the study are the incidence and severity of adverse events and serious adverse events and the incidence of dose limiting toxicities. The secondary endpoints are the overall response rate, duration or response, progression free survival, and overall survival. Learn more at ClinicalTrials.gov.

Pediatric Brain Cancer (PBC)

- The Company intends to submit an IND application to the FDA for ^{186}RNL for the treatment of PBC. The Company expects to initiate patient accrual in a Phase 1 dose escalation trial of ^{186}RNL (ReSPECT-PBC) in 2022.

Drug Manufacturing and Supply Chain

- During the third quarter of 2021, the Company entered into an agreement with RadioMedix, Inc. for the commercial production of the Company's investigational radiopharmaceuticals. Thus far in 2021, the Company has entered into five collaboration agreements to support its process development and analytical chemistry activities, as well as to strengthen its supply chain in compliance with current good manufacturing practices (GMP) for the manufacture of ^{186}RNL. The Company remains on track to deliver GMP ^{186}RNL by mid-2022.

Corporate

- During the third quarter of 2021, the Company announced the appointment of Norman LaFrance, M.D. to the position of Chief Medical Officer and Senior Vice President. Dr. LaFrance joins Plus Therapeutics with nearly 40 years of experience as a nuclear medicine physician and as an executive in the pharmaceutical and healthcare industries. Dr. LaFrance area of specialization is radiotherapeutic drug research and development as well as regulatory approval and commercialization of molecular imaging, diagnostic and therapeutic products.

UPCOMING EVENTS AND MILESTONES

Over the next 12 months, the Company intends to accomplish the following key business objectives:

- Complete enrollment of the ongoing cohort in the ReSPECT-GBM Phase 1 clinical trial.
- Fully analyze the ReSPECT-GBM Phase 1 clinical trial data and refine its Phase 2/3 clinical trial plans with the FDA.
- Initiate patient accrual in the Phase 1 ReSPECT-LM clinical trial.
- Submit an IND application to the FDA for ^{186}RNL for the treatment of patients with PBC.

- Complete CMC activities for GMP ^{186}RNL and complete CMC related meeting with the FDA.

THIRD QUARTER 2021 FINANCIAL RESULTS

- As of September 30, 2021, the Company's cash balance was $21.3 million, compared to $8.3 million as of December 31, 2020.
- Total operating expenses for the third quarter of 2021 were $3.5 million, compared to total operating expenses of $1.4 million for the same quarter in 2020. This increase is primarily due to increased research and development expenses in 2021.
- Net loss for the third quarter of 2021 was $3.7 million, or $(0.28) per share, compared to a net loss of $1.7 million, or $(0.39) per share, for the same quarter in 2020. The increase in net loss is primarily due to the aforementioned increase in research and development expenses.

Third Quarter 2021 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.

Event:	Plus Therapeutics Third Quarter 2021 Results Conference Call
Date:	Thursday, October 21, 2021
Time:	5:00 p.m. Eastern Time
Live Call:	877-876-9173 (toll free); 785-424-1667 (Intl.); Conference ID: PSTVQ321

The webcast can be accessed live via the investor section of the Plus Therapeutics website at ir.plustherapeutics.com/events and will be available for replay beginning two hours after the conclusion of the conference call.

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," "plan," "can," "design," "intend," "potential," "expect," "target," "focus," 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 Company's anticipated expenditures, including research and development, sales and marketing, and general and administrative expenses; anticipated benefits of strategic collaborations and license agreements, intellectual property, FDA approval process and government regulation; the ability of ^{186}RNL to safely and effectively deliver radiation directly to the tumor at high doses; the Company's ability to expand clinical testing of ^{186}RNL to additional sites and additional indications, such as leptomeningeal metastases and pediatric brain cancer; the Company's clinical trials including statements regarding the timing and characteristics of the ReSPECT-LM or the ReSPECT-PBC trials; the potential size of the market for the Company's product candidates; the Company's research and development efforts; the Company's IP strategy; competition; future development and/or expansion of its product candidates and therapies in its markets; its ability to obtain and maintain regulatory approvals including statements regarding the Company's intent to submit any new IND application; expectations as to the Company's future performance; the Company's need for additional financing and the availability thereof; its ability to fully access its equity line with Lincoln Park; any changes to its interest expenses; the Company's ability to continue as a going concern; operating results; and the potential enhancement of the Company's cash position through development, marketing, and licensing arrangements.

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.

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

	September 30, 2021	Decemb 202
Assets		
Current assets:		
Cash and cash equivalents	$ 21,280	$
Other current assets	817	
Total current assets	22,097	
Property and equipment, net	1,646	
Operating lease right-of-use assets	559	
Goodwill	372	
Intangible assets, net	60	
Other assets	16	
Total assets	$ 24,750	$
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,630	$
Operating lease liability	106	
Term loan obligations, net of discount	6,752	
Total current liabilities	9,488	
Noncurrent operating lease liability	504	
Warrant liability	3	
Total liabilities	9,995	
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 1,952 and 1,954 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	—	
Common stock, $0.001 par value; 100,000,000 shares authorized; 15,360,025 and 6,749,028 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	15	
Additional paid-in capital	457,495	
Accumulated deficit	(442,755)	
Total stockholders' equity	14,755	
Total liabilities and stockholders' equity	$ 24,750	$

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

	For the Three Months Ended September 30,		For the Nine Months Ended Sept	
	2021	2020	2021	
Development revenues:				
Government contracts and other	$ —	$ —	$ —	$
Operating expenses:				
Research and development	1,491	336	3,724	
In process research and development acquired from NanoTx	—	—	—	
General and administrative	1,990	1,060	4,811	
Loss on disposal of property and equipment	18	—	18	
Total operating expenses	3,499	1,396	8,553	
Loss from operations	(3,499)	(1,396)	(8,553)	
Other income (expense):				
Interest income	5	2	13	
Interest expense	(232)	(253)	(708)	
Change in fair value of warrants	2	(81)	4	
Total other income (expense)	(225)	(332)	(691)	
Net loss	$ (3,724)	$ (1,728)	$ (9,244)	$
Net loss per share, basic and diluted	$ (0.28)	$ (0.39)	$ (0.84)	$
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	13,264,230	4,402,221	10,961,284	

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

	For the Nine Months Ended September	
	2021	20
Cash flows used in operating activities:		
Net loss	$ (9,244)	$
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	266	
Amortization of deferred financing costs and debt discount	417	
Loss on disposal of property and equipment	18	
In process research and development acquired from NanoTx Therapeutics	—	
Noncash lease expenses	36	
Change in fair value of warrants	(4)	
Stock-based compensation expense	425	
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	—	
Other current assets	12	
Other assets	—	
Accounts payable and accrued expenses	418	
Net cash used in operating activities	(7,656)	
Cash flows used in investing activities:		
Purchases of property and equipment	(134)	
Proceeds from sale of property and equipment	50	
In process research and development acquired from NanoTx Therapeutics	—	
Net cash used in investing activities	(84)	
Cash flows provided by (used in) financing activities:		
Principal payments of long-term obligations	-	
Payment of financing lease liability	(8)	
Proceeds from exercise of warrants	2,017	
Proceeds from sale of common stock, net	18,665	
Net cash provided by (used in) financing activities	20,674	
Net increase (decrease) in cash and cash equivalents	12,934	
Cash and cash equivalents at beginning of period	8,346	
Cash and cash equivalents at end of period	21,280	

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