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 20, 2022

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)	**(Zip Code)**

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:

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 20, 2022, Plus Therapeutics, Inc. (the "Company") reported financial results for the quarter ended September 30, 2022 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 20, 2022.
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 thereunto duly authorized.

PLUS THERAPEUTICS, INC.

Date: October 20, 2022

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

Exhibit 99.1

Plus Therapeutics Reports Third Quarter 2022 Financial Results and Business Highlights

Awarded $17.6 million Product Development Research grant by the Cancer Prevention & Research Institute of Texas (CPRIT) to fund ^{186}RNL development for leptomeningeal metastases (LM)
Completed cGMP manufacturing objectives to support Phase 2 clinical trials for ^{186}RNL
Initiating ReSPECT-GBM Phase 2 trial for recurrent glioblastoma (GBM) in Q4 2022
Management to host conference call today at 5:00 p.m. ET

AUSTIN, Texas, October 20, 2022 – 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, 2022, and provided an overview of recent business highlights.

"The third quarter of 2022 was another period of significant progress for Plus Therapeutics, highlighted by the achievement of three key milestones," said Marc H. Hedrick M.D., President and Chief Executive Officer of Plus Therapeutics. "First, our CPRIT award of $17.6 million substantially funds the LM program through Phase 2 for our lead investigational drug, Rhenium-186 Nanoliposome (^{186}RNL). Second, we moved ^{186}RNL toward a Phase 2 trial for recurrent GBM, which we expect to initiate in the fourth quarter of 2022. Third, we met our timeline for cGMP ^{186}RNL drug availability for all future trials. In addition, the combination of current cash, access to funding, and grant funding, secures our cash runway through 2025."

RECENT HIGHLIGHTS

- On September 9, 2022, Dr. Andrew Brenner, ReSPECT-GBM trial principal investigator, presented Phase 1 results from the ReSPECT-GBM Phase 1/2a dose escalation trial evaluating ^{186}RNL in patients with recurrent GBM at the European Society for Medical Oncology (ESMO) Congress 2022. The Phase 1 results demonstrated safety and a potential efficacy signal in a heavily pretreated group of patients with recurrent GBM.
- On August 17, 2022, Plus Therapeutics announced the award of a three-year, $17.6 million Product Development Research grant by the Cancer Prevention & Research Institute of Texas (CPRIT) to fund ^{186}RNL for the treatment of patients with LM.
- On August 29, 2022, Plus announced a summary of its Type C meeting with the U.S. Food and Drug Administration (FDA) regarding the CMC program for ^{186}RNL. The Company determined that it may proceed in utilizing its ^{186}RNL in its planned Phase 2 programs.
- On September 6, 2022, Plus announced a summary of its Type C meeting with the FDA regarding its clinical development program for ^{186}RNL for recurrent GBM. Based on that meeting, the Company plans to begin a Phase 2 trial of ^{186}RNL in patients with recurrent GBM, with a focus on small and medium-sized tumors. The Company will also continue exploration of both higher and multiple doses of ^{186}RNL.
- The Company initiated enrollment of Cohort 2 of the ReSPECT-LM Phase 1/2a dose escalation trial of ^{186}RNL in patients with LM.

- On October 18, 2022, at the 35th Annual Congress of the European Association of Nuclear Medicine (EANM), the Company presented data from two ongoing clinical trials evaluating ^{186}RNL in recurrent GBM and LM. The findings presented at EANM indicate the potential for ^{186}RNL as a safe, well-tolerated and promising radiotherapeutic for both GBM and LM.

THIRD QUARTER 2022 FINANCIAL RESULTS

- The Company's cash balance was $20.3 million at September 30, 2022, compared to $18.4 million at December 31, 2021. The Company believes that cash on hand and anticipated funding from the National Institute of Health (NIH) and CPRIT are sufficient to fund both its currently planned overhead and development expenses through 2025.
- Grant revenue of $73,000 was recognized in the third quarter of 2022, which represents CPRIT's share of the costs incurred for development of ^{186}RNL for the treatment of patients with LM. The Company continues to expect the initial CPRIT grant funds of approximately $1.9 million to be disbursed to the Company by October 31, 2022.
- Total operating expenses for the third quarter of 2022 were $5.2 million, compared to total operating expenses of $3.5 million for third quarter of 2021. The increase is due primarily to incremental CMC spend relating to the development of GMP ^{186}RNL drug and key regulatory consulting activities. In addition, to a lesser extent, the Company had a forecasted increase in legal, professional fees and other general corporate expenses.
- Net loss for the third quarter of 2022 was $5.2 million, or $(0.19) per share, compared to a net loss of $3.7 million, or $(0.28) per share, for the third quarter of 2021.

UPCOMING EVENTS AND MILESTONES

During the remainder of 2022, the Company expects to accomplish the following key business objectives:

- ReSPECT-GBM Phase 2 clinical trial initiation
- Present updated data from the ReSPECT-GBM and ReSPECT-LM trials at the Society for Neuro-Oncology (SNO) Annual Meeting and Education Day, November 17-20, 2022
- Complete Cohort 2 of ReSPECT-LM Phase 1/2a dose escalation trial
- Submit an Investigational New Drug (IND) application to the FDA for the study of ^{186}RNL in patients with pediatric brain cancer (ReSPECT-PBC), epedymoma and high-grade glioma
- Complete key CMC and IND-enabling studies for ^{188}RNL-BAM

Third Quarter 2022 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.

A live webcast will be available at ir.plustherapeutics.com/events.

Participants may also pre-register any time before the call here. 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 'For Investor'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 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-GBM and ReSPECT-LM clinical trials; possible negative effects of ^{186}RNL; the continued evaluation of ^{186}RNL 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.

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 20,266	$ 18,400
Grant receivable	73	—
Other current assets	540	1,324
Total current assets	20,879	19,724
Property and equipment, net	1,453	1,477
Operating lease right-use-of assets	275	341
Goodwill	372	372
Intangible assets, net	113	51
Other assets	12	16
Total assets	$ 23,104	$ 21,981
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 5,705	$ 4,151
Operating lease liability	107	111
Term loan obligation, current	1,608	1,608
Total current liabilities	7,420	5,870
Noncurrent operating lease liability	172	269
Term loan obligation	4,108	5,005
Warrant liability	—	1
Total liabilities	11,700	11,145
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 1,952 shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized; 32,570,002 and 15,510,025 issued and outstanding at September 30, 2022 and December 31, 2021, respectively	32	16
Additional paid-in capital	472,899	457,730
Accumulated deficit	(461,527)	(446,910)
Total stockholders' equity	11,404	10,836
Total liabilities and stockholders' equity	$ 23,104	$ 21,981

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 September 30,	
	2022	2021	2022	2021
Grant revenue	$ 73	$ —	$ 73	$ —
Operating expenses:				
Research and development	2,945	1,491	7,560	3,724
General and administrative	2,222	1,990	6,653	4,811
Loss on disposal of property and equipment	—	18	—	18
Total operating expenses	5,167	3,499	14,213	8,553
Operating loss	(5,094)	(3,499)	(14,140)	(8,553)
Other income (expense):				
Interest income	48	5	74	13
Interest expense	(173)	(232)	(552)	(708)
Change in fair value of liability instruments	—	2	1	4
Total other expense	(125)	(225)	(477)	(691)
Net loss	$ (5,219)	$ (3,724)	$ (14,617)	$ (9,244)
Net loss per share, basic and diluted	$ (0.19)	$ (0.28)	$ (0.61)	$ (0.84)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	27,441,654	13,264,230	23,789,195	10,961,284

CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS
(UNAUDITED)
(in thousands)

	For the Nine Months Ended September 30,	
	2022	2021
Cash flows used in operating activities:		
Net loss	$ (14,617)	$ (9,244)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	460	266
Amortization of deferred financing costs and debt discount	309	417
In process research and development acquired	—	18
Change in fair value of liability instruments	(1)	(4)
Stock-based compensation expense	476	425
Non-cash lease expense	(35)	36
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Grant receivable	73	—
Other current assets	642	12
Accounts payable and accrued expenses	1,955	418
Net cash used in operating activities	(10,738)	(7,656)
Cash flows used in investing activities:		
Purchases of property and equipment	(381)	(134)
Purchase of intangible assets	(117)	
Proceeds from sale of property and equipment	—	50
In process research and development acquired	(250)	—
Net cash used in investing activities	(748)	(84)
Cash flows from financing activities:		
Principal payments of long-term obligations	(1,206)	—
Payment of financing lease liability	—	(8)
Proceeds from exercise of warrants	—	2,017
Proceeds from sale of common stock, net	14,558	18,665
Net cash provided by financing activities	13,352	20,674
Net increase in cash and cash equivalents	1,866	12,934
Cash and cash equivalents at beginning of period	18,400	8,346
Cash and cash equivalents at end of period	$ 20,266	$ 21,280
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	$ 248	$ 292
Supplemental schedule of non-cash investing and financing activities:		
Unpaid offering cost	$ 68	$ 139
Right-of-use asset obtained in exchange for lease liabilities	$ —	$ 81

Investor Contact
Peter Vozzo
ICR Westwicke
(443) 377-4767
Peter.Vozzo@westwicke.com

Media Contact
Terri Clevenger
ICR Westwicke
(203) 856-4326
Terri.Clevenger@westwicke.com