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): August 14, 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)	**(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 August 14, 2023, Plus Therapeutics, Inc. (the "Company") reported financial results for the second quarter ended June 30, 2023 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 August 14, 2023.
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.

PLUS THERAPEUTICS, INC.

Date: August 14, 2023

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

Exhibit 99.1

Plus Therapeutics Reports Second Quarter 2023 Financial Results and Business Highlights

ReSPECT clinical trial data continues to demonstrate promise for treatment of leptomeningeal metastases and recurrent glioblastoma

Received FDA approval to move into Phase 1/Part B of the ReSPECT-LM clinical trial

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

AUSTIN, Texas, August 14, 2023 – 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 financial results for the second quarter ended June 30, 2023, and provided an overview of recent business highlights.

"The past 12 months have been transformative for the company," said Marc H. Hedrick M.D., President and Chief Executive Officer of Plus Therapeutics. "We now have two lead indications, recurrent glioblastoma and leptomeningeal metastases, for our rhenium (^{186}Re) obisbemeda investigational drug and we plan to fully leverage available external third-party funding to move both clinical development programs through Phase 2 and evaluate accelerated approval opportunities."

Q2 HIGHLIGHTS AND MILESTONE ACHIEVEMENTS

Leptomeningeal Metastases

- Completed Phase 1/Part A of the ReSPECT-LM clinical trial.
- Presented preliminary safety and efficacy results from Phase 1/Part A of the ReSPECT-LM clinical trial at the Society for Neuro Oncology (SNO)/American Society of Clinical Oncology (ASCO) Central Nervous System (CNS) Cancer Conference.
- Received U.S. Food and Drug Administration (FDA) approval to move to Phase 1/Part B of the ReSPECT-LM clinical trial.
- In the second quarter of 2023, achieved all Year 1 goals and objectives set forth in the Company's 3-Year, $17.6M Cancer Prevention & Research Institute of Texas (CPRIT) grant.

Recurrent Glioblastoma

- Presented clinical updates on the ReSPECT-GBM Phase 1 dose escalation and Phase 2b trials for recurrent glioblastoma (GBM) at the SNO/ ASCO CNS Cancer Conference.
- Announced topline results from our propensity matched, recurrent GBM external control analysis for comparative evaluation of outcomes in our prospective recurrent glioblastoma trials at American Society of Clinical Oncology (ASCO) 2023.

Supply Chain

- Expanded collaboration with Piramal Pharma Solutions to produce additional cGMP liposome intermediate drug product to meet the increase in demand for rhenium (^{186}Re) obisbemeda in ongoing and planned clinical trials.

Organization

- Strengthened clinical development leadership with the appointment of Pius Maliakal, M. Pharm., Ph.D., as Vice President of Clinical Operations.

SECOND QUARTER 2023 FINANCIAL RESULTS

- The Company's cash balance was $10.9 million at June 30, 2023, compared to $18.1 million at December 31, 2022. A second grant payment from CPRIT, in the amount of $1.9 million, has been approved and is expected to be received prior to the end of August 2023.
- The Company recognized $1.9 million of grant revenue in the second quarter of 2023, which represents the CPRIT's share of costs incurred in the development of rhenium (^{186}Re) obisbemeda for the treatment of patients with LM.
- Total operating expenses for the second quarter of 2023 were $3.3 million, compared to total operating expenses of $5.1 million for the same period the prior year. The decrease is due primarily to a decrease in research and development expenses from completion of the initial cGMP development work on rhenium (^{186}Re) obisbemeda.
- In addition to current cash on hand, the Company benefits from grant awards of $3 million from the National Institutes of Health and $17.6 million from CPRIT. The Company also has discretionary, or stockholder approved access to capital, subject to market conditions and securities laws compliance from its ATM and equity line of credit of at least $49 million. In aggregate, these capital sources could provide sufficient capital to fund currently planned and anticipated activities through 2025, if fully utilized.
- Net loss for the second quarter of 2023 was $(1.5) million, or $(0.59) per share, compared to a net loss of $(5.3) million, or $(3.56) per share, for the same period the prior year.

UPCOMING 2023 EVENTS AND MILESTONES

During the remainder of 2023, the Company plans to accomplish the following key business objectives:

- Initiate Phase 1/Part B of the ReSPECT-LM trial.
- Obtain FDA approval and initiate the Phase 1 ReSPECT-PBC trial for pediatric patients with ependymoma and high-grade glioma at Lurie Children's Hospital in Chicago.
- Determine FDA regulatory designation for the ^{188}RNL-BAM development.
- Add key second source supply chain vendors to support late-stage clinical trials.
- Publish ReSPECT-GBM Phase 1 data in peer-reviewed publication.
- Present safety and efficacy data from ReSPECT-GBM trials at the annual SNO conference in Vancouver on November 16-19, 2023.

- Various data presentations planned for the following 2023 medical meetings: EANM on September 9-13 and CPRIT's Innovations in Cancer Prevention and Research Conference VI on October 2-3.

SECOND QUARTER 2023 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 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; possible negative effects of ^{186}Re; the continued evaluation of ^{186}Re including through evaluations in additional patient cohorts; the intended functions of the Company's platform and expected benefits from such functions; and matters regarding the Company's liquidity and access to capital.

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. 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, and 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, including because of market conditions and limitations under the securities laws given the Company's current market capitalization: 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.
CONDENSED BALANCE SHEETS
(UNAUDITED)
(in thousands, except share and par value data)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 10,895	$ 18,120
Grant receivable	718	—
Other current assets	751	3,697
Total current assets	12,364	21,817
Property and equipment, net	1,143	1,324
Operating lease right-of-use assets	242	248
Goodwill	372	372
Intangible assets, net	64	94
Other assets	12	12
Total assets	$ 14,197	$ 23,867
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 6,580	$ 10,134
Operating lease liability	110	110
Term loan obligation	4,709	1,608
Total current liabilities	11,399	11,852
Term loan obligation	—	3,786
Noncurrent operating lease liability	136	141
Deferred grant liability	—	1,643
Total liabilities	11,535	17,422
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 1,952 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized; 2,879,620 and 2,240,092 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	3	2
Additional paid-in capital	476,131	473,628
Accumulated deficit	(473,472)	(467,185)
Total stockholders' equity	2,662	6,445
Total liabilities and stockholders' equity	$ 14,197	$ 23,867

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2023	2022	2023	2022
Development revenues:				
Government contracts and other	$ 1,854	$ —	$ 2,360	$ —
Operating expenses:				
Research and development	1,420	2,831	4,403	4,615
General and administrative	1,924	2,289	4,167	4,431
Total operating expenses	3,344	5,120	8,570	9,046
Loss from operations	(1,490)	(5,120)	(6,210)	(9,046)
Other income (expense):				
Interest income	120	19	171	26
Interest expense	(112)	(181)	(246)	(379)
Loss on disposal of property and equipment	—	—	(2)	—
Change in fair value of liability instruments	—	—	—	1
Total other income (expense)	8	(162)	(77)	(352)
Net loss	$ (1,482)	$ (5,282)	$ (6,287)	$ (9,398)
Net loss per share, basic and diluted	$ (0.59)	$ (3.56)	$ (2.60)	$ (6.43)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	2,509,378	1,483,655	2,415,221	1,461,330

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

	For the Six Months Ended June 30,	
	2023	**2022**
Cash flows used in operating activities:		
Net loss	$ (6,287)	$ (9,398)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	318	302
Amortization of deferred financing costs and debt discount	119	218
Change in fair value of liability instruments	—	(1)
Loss on disposal of property and equipment	2	—
Stock-based compensation expense	280	347
Amortization of operating lease right-of-use assets	57	38
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Grant receivable	718	—
Other current assets	1,510	525
Accounts payable and accrued expenses	(3,589)	1,527
Change in operating lease liabilities	(56)	(74)
Deferred revenue	(1,643)	—
Net cash used in operating activities	(8,571)	(6,516)
Cash flows used in investing activities:		
Purchases of property and equipment	(108)	(348)
Purchase of intangible assets	—	(117)
In process research and development acquired	—	(250)
Net cash used in investing activities	(108)	(715)
Cash flows from financing activities:		
Principal payments of term loan obligation	(804)	(804)
Proceeds from sale of common stock, net	2,258	7,725
Net cash provided by financing activities	1,454	6,921
Net decrease in cash and cash equivalents	(7,225)	(310)
Cash and cash equivalents at beginning of period	18,120	18,400
Cash and cash equivalents at end of period	$ 10,895	$ 18,090
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	$ 135	$ 168
Supplemental schedule of non-cash investing and financing activities:		
Unpaid offering cost	$ 35	$ 50

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