

**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 31, 2023

PLUS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-34375
(Commission
File Number)

33-0827593
(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 2.02 Results of Operations and Financial Condition.

On October 31, 2023, Plus Therapeutics, Inc. (the “Company”) reported financial results for the third quarter ended September 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 October 31, 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.

Date: October 31, 2023

PLUS THERAPEUTICS, INC.

By: /s/ Marc H. Hedrick, M.D.

Marc H. Hedrick, M.D.

President and Chief Executive Officer

Plus Therapeutics Reports Third Quarter 2023 Financial Results and Business Highlights

New survival data from 15 patients in the Phase 2 ReSPECT-GBM trial of rhenium (¹⁸⁶Re) obisbameda in recurrent glioblastoma (rGBM) will be presented at SNO Annual Meeting on November 17th; Company will also host a Key Opinion Leader (KOL) event following the meeting to discuss the results

Completed dosing in Cohort 4 of the Phase 1 ReSPECT-LM dose escalation trial with rhenium (¹⁸⁶Re) obisbameda for leptomeningeal metastases, the first of four additional planned cohorts in Part B (Cohorts 4-7); an update will also be provided at the SNO meeting in November

Current cash of \$11 million, plus an additional \$10.2 million expected through the end of 2024 from the Cancer Prevention & Research Institute of Texas (CPRIT) grant, should provide sufficient runway to fund operations into 2025

Management to Host Conference Call Today at 5:00 p.m. ET

AUSTIN, Texas, October 31, 2023 (GLOBE NEWSWIRE) – 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 third quarter ended September 30, 2023, and provided an overview of recent and upcoming business highlights.

“Our active trials of Rhenium-186 Obisbameda continue to show encouraging results in treating both recurrent glioblastoma and leptomeningeal metastases and we will provide significant updates on both trials at the Society for Neuro-Oncology (SNO) Annual Meeting and at our KOL event following the meeting in November,” said Marc H. Hedrick M.D., President and Chief Executive Officer of Plus Therapeutics. “Furthermore, our current balance sheet and forecasted grant payments from CPRIT, which will continue through August 2025, should be sufficient to provide a cash runway into 2025.”

UPCOMING EVENTS AND MILESTONES

Through the remainder of 2023 and 2024, the Company plans to accomplish the following key business objectives:

- Present the latest safety and efficacy data from the Phase 2 ReSPECT-GBM trial at the annual SNO meeting in Vancouver on November 15-19, 2023.
- Present the latest safety and efficacy data from the Phase 1 ReSPECT-LM trial at the annual SNO meeting in Vancouver on November 15-19, 2023.
- Participate in virtual KOL webinar following SNO meeting to discuss GBM data presented at the SNO meeting.
- Complete enrollment in the Phase 2 ReSPECT-GBM trial and finalize pivotal design with FDA.
- Complete enrollment in the Phase 1 ReSPECT-LM trial and begin phase 2 trial.
- Complete internal implementation of the CNSide™ cerebrospinal fluid (CSF)-based biomarker and tumor cell capture and enumeration assay being utilized in the ReSPECT-LM clinical trial.
- Obtain FDA IND approval and initiate the Phase 1 ReSPECT-PBC trial for pediatric patients with ependymoma and high-grade glioma at the Lurie Children’s Hospital in Chicago.
- Complete key development milestones for the company’s next generation radioembolic device ¹⁸⁸RNL-BAM.
- Add key second source GMP supply chain partners to support late-stage clinical trials and commercial supply.
- Publish ReSPECT-GBM Phase 1 data in a peer-reviewed publication.

Q3 HIGHLIGHTS AND MILESTONE ACHIEVEMENTS

- Completed dosing in Cohort 4 of the ReSPECT-LM Phase 1/2a dose escalation trial of rhenium (^{186}Re) obisbameda for the treatment of LM. Cohort 4 is the first of 4 planned cohorts in Part B.
- Presented preliminary safety and efficacy results from Phase 1/Part A of the ReSPECT-LM clinical trial at the SNO/ASCO CNS Cancer Conference. Following the presentation, the Company hosted a key opinion leader roundtable on data presented at the conference.
- Received advance payment of grant funds of approximately \$1.9 million from CPRIT, as planned, as part of its overall \$17.6 million award contract.
- Completed transfer of proprietary materials, protocols, and equipment from Biocept for the CNSide, a cerebrospinal fluid (CSF)-based biomarker and tumor cell capture and enumeration assay being utilized in the ReSPECT-LM clinical trial.
- Strengthened clinical development leadership with the appointment of Pius Maliakal, M. Pharm., Ph.D., as Vice President of Clinical Operations.

THIRD QUARTER 2023 FINANCIAL RESULTS

- The Company's cash balance was \$11.0 million at September 30, 2023, compared to \$18.1 million at December 31, 2022.
- The Company recognized \$1.2 million in grant revenue in the third quarter of 2023, which represents CPRIT's share of the costs incurred for our rhenium (^{186}Re) obisbameda development for the treatment of patients with LM.
- Total operating expenses for the third quarter of 2023 were \$4.5 million, compared to total operating expenses of \$5.2 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) obisbameda.
- 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.
- Net loss for the third quarter of 2023 was \$(3.2) million, or \$(1.00) per share, compared to a net loss of \$(5.2) million, or \$(2.85) per share, for the same period the prior year.

THIRD QUARTER RESULTS CONFERENCE CALL

The Company will hold a conference call and live audio webcast at 5:00 pm 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 Investors](#)' 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; 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.

Investor Contact

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 11,006	\$ 18,120
Grant receivable	91	—
Other current assets	487	3,697
Total current assets	11,584	21,817
Property and equipment, net	1,009	1,324
Operating lease right-of-use assets	232	248
Goodwill	372	372
Intangible assets, net	49	94
Other assets	32	12
Total assets	<u>\$ 13,278</u>	<u>\$ 23,867</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,073	\$ 10,134
Operating lease liability	117	110
Term loan obligation	4,348	1,608
Total current liabilities	10,538	11,852
Term loan obligation	—	3,786
Noncurrent operating lease liability	118	141
Deferred grant liability	—	1,643
Total liabilities	10,656	17,422
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 1,952 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 4,522,656 and 2,240,092 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	5	2
Additional paid-in capital	479,308	473,628
Accumulated deficit	(476,691)	(467,185)
Total stockholders' equity	2,622	6,445
Total liabilities and stockholders' equity	<u>\$ 13,278</u>	<u>\$ 23,867</u>

PLUS THERAPEUTICS, INC.
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,	
	2023	2022	2023	2022
Grant Revenue	\$ 1,240	\$ 73	\$ 3,600	\$ 73
Operating expenses:				
Research and development	2,493	2,945	6,896	7,560
General and administrative	1,998	2,222	6,165	6,653
Total operating expenses	<u>4,491</u>	<u>5,167</u>	<u>13,061</u>	<u>14,213</u>
Loss from operations	(3,251)	(5,094)	(9,461)	(14,140)
Other income (expense):				
Interest income	119	48	290	74
Interest expense	(87)	(173)	(333)	(552)
Loss on disposal of property and equipment	—	—	(2)	—
Change in fair value of liability instruments	—	—	—	1
Total other income (expense)	<u>32</u>	<u>(125)</u>	<u>(45)</u>	<u>(477)</u>
Net loss	<u>\$ (3,219)</u>	<u>\$ (5,219)</u>	<u>\$ (9,506)</u>	<u>\$ (14,617)</u>
Net loss per share, basic and diluted	\$ (1.00)	\$ (2.85)	\$ (3.54)	\$ (9.22)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	3,225,351	1,829,444	2,688,232	1,585,946

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

	For the Nine Months Ended	
	September 30,	
	2023	2022
Cash flows used in operating activities:		
Net loss	\$ (9,506)	\$ (14,617)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	477	460
Amortization of deferred financing costs and debt discount	160	309
Stock issued for research and development	75	—
Loss on disposal of property and equipment	2	—
Stock-based compensation expense	428	476
Change in fair value of derivative instruments	—	(1)
Amortization of operating lease right-of-use assets	86	66
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Grant receivable	(91)	73
Other assets	3,190	642
Accounts payable and accrued expenses	(4,061)	1,955
Change in operating lease liabilities	(87)	(101)
Deferred grant liability	(1,643)	—
Net cash used in operating activities	<u>(10,970)</u>	<u>(10,738)</u>
Cash flows used in investing activities:		
Purchases of property and equipment	(118)	(381)
Purchase of intangible assets	—	(117)
In process research and development acquired	—	(250)
Net cash used in investing activities	<u>(118)</u>	<u>(748)</u>
Cash flows from financing activities:		
Principal payments of term loan obligation	(1,206)	(1,206)
Proceeds from sale of common stock, net of offering cost of \$0.2 million	5,180	14,558
Net cash provided by financing activities	<u>3,974</u>	<u>13,352</u>
Net increase (decrease) in cash and cash equivalents	<u>(7,114)</u>	<u>1,866</u>
Cash and cash equivalents at beginning of period	18,120	18,400
Cash and cash equivalents at end of period	<u>\$ 11,006</u>	<u>\$ 20,266</u>
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	\$ 186	\$ 248
Supplemental schedule of non-cash investing and financing activities:		
Unpaid offering cost	\$ 1	\$ 68
Right-of-use assets acquired by assuming operating lease liabilities	\$ 71	\$ —
Common stock issued in payment for in process research and development	\$ 75	\$ —