

**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): February 23, 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
(Address of Principal Executive Offices)

78756
(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 February 23, 2023, Plus Therapeutics, Inc. (the “Company”) reported financial results for the fourth quarter and year ended December 31, 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 February 23, 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: February 23, 2023

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

Plus Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Business Highlights

Initiated ReSPECT-GBM Phase 2 and ReSPECT- LM Phase 1 trials for CNS cancers

Awarded \$17.6 million Cancer Prevention & Research Institute of Texas (CPRIT) grant to support clinical development of rhenium (¹⁸⁶Re) obisbameda for leptomeningeal metastases (LM)

Cash, grant funding, and discretionary capital sources expected to be sufficient to fund expenses through 2025

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

AUSTIN, Texas, February 23, 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 fourth quarter and year ended December 31, 2022, and provided an overview of recent business highlights.

“During 2022, we made significant progress in our co-lead radiotherapeutic programs for recurrent glioblastoma (GBM) and LM. Furthermore, even during a turbulent time in the U.S. capital markets, we reached a new level of balance sheet stability to support our exciting and potentially game-changing targeted radiotherapeutic drug candidates,” said Marc H. Hedrick M.D., President and Chief Executive Officer of Plus Therapeutics. “In 2023, we intend to build on the success of 2022 to simultaneously advance our active programs in GBM and LM and also broaden and diversify our drug development pipeline.”

2022 AND 2023 HIGHLIGHTS AND MILESTONE ACHIEVEMENTS

- Completed multi-year program, including related U.S. Food and Drug Administration (FDA) interactions, to produce GMP rhenium (¹⁸⁶Re) obisbameda for Phase 2 clinical trials.
 - Enrolled first patient in the Phase 2b clinical trial of rhenium (¹⁸⁶Re) obisbameda for recurrent GBM. Presented data from the ReSPECT-GBM Phase 1/2a dose escalation trial evaluating rhenium (¹⁸⁶Re) obisbameda in patients with recurrent GBM at the 27th Annual Scientific Meeting and Education Day of the Society for Neuro-Oncology (SNO).
 - Awarded \$17.6 million CPRIT grant to support Phase 1 and Phase 2 clinical development of rhenium (¹⁸⁶Re) obisbameda for LM.
 - Completed enrollment in the second cohort of the ReSPECT-LM Phase 1 clinical trial of rhenium (¹⁸⁶Re) obisbameda for the treatment of LM.
 - Presented initial clinical experience from the ReSPECT-LM Phase 1/2a dose escalation trial evaluating rhenium (¹⁸⁶Re) obisbameda in patients with LM at the 27th Annual Scientific Meeting and Education Day of SNO.
 - Engaged with the FDA on proposed Investigational New Drug (IND) application to treat pediatric patients with ependymoma and high-grade glioma.
 - Licensed bioresorbable radio-embolic technology platform (¹⁸⁶RNL-BAM) from the University of Texas and completed key manufacturing and preclinical human *ex vivo* and proof of concept activities as well as initial FDA interactions.
 - Announced a comprehensive laboratory services agreement with Biocept to use the CNSide assay to evaluate response to treatment and treatment efficacy in the ReSPECT-LM clinical trial.
 - Executed a variety of agreements and transactions to supplement the balance sheet and raised capital expected to be sufficient to fund expenses through 2025.
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FULL YEAR 2022 FINANCIAL RESULTS

- The Company's cash balance was \$18.1 million at December 31, 2022, compared to \$18.4 million at December 31, 2021. The Company believes that current cash on hand, anticipated funding from both the National Institutes of Health and CPRIT, and existing discretionary capital sources are sufficient to fund both its currently planned and anticipated overhead and development expenses through 2025.
- Grant revenue of \$224,000 was recognized for full year 2022, which represents CPRIT's initial share of the costs incurred for development of ¹⁸⁶RNL for the treatment of patients with LM. During the fourth quarter of 2022, the Company received its first CPRIT grant funds of approximately \$1.9 million.
- Total operating expenses for full year 2022 were \$19.9 million, compared to total operating expenses of \$12.5 million for full year 2021. The increase is due primarily to incremental CMC spend related to the development of GMP ¹⁸⁶RNL drug and key regulatory consulting activities. In addition, to a lesser extent, the Company had a one-time forecasted increase in general corporate expenses together with litigation and legal expenses primarily related to resolving a legal dispute.
- Net loss for full year 2022 was \$20.3 million, or \$(0.77) per share, compared to a net loss of \$13.4 million, or \$(1.11) per share, for full year 2021.

UPCOMING EVENTS AND MILESTONES

During 2023, the Company expects to accomplish the following key business objectives:

- Expand clinical sites and make enrollment progress of the ReSPECT-GBM Phase 2b trial to support enrollment completion by the end of 2024.
- Publish ReSPECT-GBM Phase 1 data in a peer reviewed journal.
- Present safety and efficacy data from ReSPECT-GBM Phase 1/2a dose escalation trial and ReSPECT-GBM Phase 2b dose expansion trial in the second half of 2023.
- Complete enrollment in Phase 1/Part A of the ReSPECT-LM trial, expand the number of trial sites, and begin enrollment in Phase 1/Part B.
- Present clinical safety and efficacy data of Phase 1/Part A of the ReSPECT-LM trial in the second half of 2023.
- Explore potentially synergistic drug combination studies of locally delivered rhenium (¹⁸⁶Re) obisbameda and promising systemic therapies in relevant preclinical models of LM.
- Finalize and submit an FDA IND application to treat pediatric patients with ependymoma and high-grade glioma and begin enrollment.
- In conjunction with the FDA, finalize regulatory designation of ¹⁸⁶RNL-BAM technology and complete key development activities.
- Execute corporate partnerships to expand the business opportunities for Plus Therapeutics' unique CNS oncology platform.
- Submit multiple grants to secure non-dilutive capital to support expansion of the Company's drug development pipeline.

FOURTH QUARTER AND FULL YEAR 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 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. 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," "expects," "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 186RNL including the ability of 186RNL 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; statements with respect to the Company's capital resources; 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 186RNL; the continued evaluation of 186RNL 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.
BALANCE SHEETS
(in thousands, except share and par value data)

	As of December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 18,120	\$ 18,400
Other current assets	3,697	1,324
Total current assets	21,817	19,724
Property and equipment, net	1,324	1,477
Operating lease right-use-of assets	248	341
Goodwill	372	372
Intangible assets, net	94	51
Other assets	12	16
Total assets	\$ 23,867	\$ 21,981
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 10,134	\$ 4,151
Operating lease liability	110	111
Term loan obligation, current	1,608	1,608
Total current liabilities	11,852	5,870
Noncurrent operating lease liability	141	269
Term loan obligation	3,786	5,005
Deferred grant liability	1,643	—
Warrant liability	—	1
Total liabilities	17,422	11,145
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 1,952 shares issued and outstanding as of December 31, 2022 and 2021	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 33,601,373 and 15,510,025 shares issued and outstanding as of December 31, 2022 and 2021, respectively	34	16
Additional paid-in capital	473,596	457,730
Accumulated deficit	(467,185)	(446,910)
Total stockholders' equity	6,445	10,836
Total liabilities and stockholders' equity	\$ 23,867	\$ 21,981

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

	For the Years Ended December 31,	
	2022	2021
Grant revenue	\$ 224	\$ —
Operating expenses:		
Research and development	9,698	5,323
In process research and development acquired	—	250
General and administrative	10,238	6,853
Loss on disposal of property and equipment	—	66
Total operating expenses	<u>19,936</u>	<u>12,492</u>
Operating loss	<u>(19,712)</u>	<u>(12,492)</u>
Other income (expense):		
Interest income	147	19
Interest expense	(711)	(932)
Change in fair value of liability instruments	1	6
Total other expense	<u>(563)</u>	<u>(907)</u>
Net loss	<u>\$ (20,275)</u>	<u>\$ (13,399)</u>
Net loss per share, basic and diluted	\$ (0.77)	\$ (1.11)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	26,255,256	12,089,186

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

	For the Years Ended December 31,	
	2022	2021
Cash flows used in operating activities:		
Net loss	\$ (20,275)	\$ (13,399)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	619	395
Amortization of deferred financing costs and debt discount	389	546
In process research and development acquired	—	250
Change in fair value of liability instruments	(1)	(6)
Loss on disposal of property and equipment	—	66
Share-based compensation expense	606	606
Amortization of operating lease right-of-use assets	93	24
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Other current assets	(2,369)	(496)
Accounts payable and accrued expenses	6,452	1,734
Change in operating lease liabilities	(129)	-
Other long-term liabilities	1,643	—
Net cash used in operating activities	<u>(12,972)</u>	<u>(10,280)</u>
Cash flows used in investing activities:		
Purchases of property and equipment and intangible assets	(509)	(144)
In process research and development acquired	(250)	—
Proceeds from sale of property and equipment	—	62
Net cash used in investing activities	<u>(759)</u>	<u>(82)</u>
Cash flows from financing activities:		
Principal payments of long-term obligations	(1,608)	(268)
Payment of finance lease liability	—	(8)
Proceeds from exercise of warrants	—	2,017
Proceeds from sale of common stock	15,059	18,675
Net cash provided by financing activities	<u>13,451</u>	<u>20,416</u>
Net increase (decrease) in cash and cash equivalents	(280)	10,054
Cash and cash equivalents at beginning of period	18,400	8,346
Cash and cash equivalents at end of period	<u>\$ 18,120</u>	<u>\$ 18,400</u>
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	\$ 327	\$ 388
Supplemental schedule of non-cash investing and financing activities:		
Unpaid offering cost	\$ —	\$ 219

Investor Contact

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